CHARGE OF DISCRIMINATION

This form is affected by the Privacy Act of 1974. See enclosed Privacy Act Statement and other information before completing this form.

Charge Presented To: Agency(ies) Charge No(s):

- ☐ FEPA
- ☒ EEOC

and EEOC

State or local Agency, if any

Name (Indicate Mr., Ms., Mrs.)	Home Phone (Incl. Area Code)	Date of Birth
David Platta (represented by Jeanne Bynum Hipes, Esq., Hipes Law LLC (678-867-7006))	7068889888	7/14/59

Street Address: 6214 Goodwin Drive, Columbus, GA 31909 — City, State and ZIP Code

Named is the Employer, Labor Organization, Employment Agency, Apprenticeship Committee, or State or Local Government Agency That I Believe Discriminated Against Me or Others. (*If more than two are named, list under PARTICULARS below.*)

Name	No. Employees, Members	Phone No. (Incl. Area Code)
Gray Television, Inc. (dba WTVM-Columbus) (rep. by Natalie Turner, Esq. (404-870-1735)	8,000+ nationwide	4042668333

Street Address: 4370 Peachtree Road, NE Suite 400 Atlanta, GA 30319 — City, State and ZIP Code

Name	No. Employees, Members	Phone No. (Incl. Area Code)

Street Address: — City, State and ZIP Code

DISCRIMINATION BASED ON (*Check appropriate box(es).*)

- ☐ RACE ☐ COLOR ☐ SEX ☒ RELIGION ☐ NATIONAL ORIGIN
- ☒ RETALIATION ☐ AGE ☐ DISABILITY ☐ GENETIC INFORMATION
- ☐ OTHER (*Specify*)

DATE(S) DISCRIMINATION TOOK PLACE

Earliest: Aug 2021 Latest: Sept 15, 2021

☐ CONTINUING ACTION

THE PARTICULARS ARE (*If additional paper is needed, attach extra sheet(s)*):

In violation of Title VII of the Civil Rights Act of 1964 (Pub. L. 88-352) (Title VII), as amended, the U.S. Constitution, and other laws, Gray Television, Inc ("Gray TV") has failed and refused to accommodate Mr. Platta's sincerely held religous beliefs, and has disccriminated and retaliated against him by terminating him after 36 years of loyal, stellar service to Gray TV--in breach of his 3-year employment contract. Mr. Platta properly and timeley asserted his religious beliefs on a form provided by Gray TV and requested an accommodation to the COVID-19 vaccine mandate imposed improperly by Gray on all its employees. Without any interactive discussion, Gray TV summarily denied all accommodations reasonably proposed by Mr. Platta and terminated him effective September 15, 2021. Gray has offered no evidence, much less proof, that the accommodations suggested by Mr. Platta would cause Gray undue hardship. In fact, such accommodations would present no hardship to Gray TV whatsoever.

Mr. Platta urges the EEOC to promptly investigate this matter, and find Gray liable for violation of Mr. Platta's rights to religious freedom under Title VII, the U.S. Constitution and other laws, and ensure that he is made whole by compensating him for the significant damages Mr. Platta has suffered as a result of Gray TV's illegal conduct, as set forth in more detail on the attached Narrative.

Please see attached Narrative, incorporated herein by reference.

I want this charge filed with both the EEOC and the State or local Agency, if any. I will advise the agencies if I change my address or phone number and I will cooperate fully with them in the processing of my charge in accordance with their procedures.

I declare under penalty of perjury that the above is true and correct.

11-22-2021 David Platta
Date — Charging Party Signature

NOTARY – *When necessary for State or Local Agency Requirements*

I swear or affirm that I have read the above charge and that it is true to the best of my knowledge, information and belief.

SIGNATURE OF COMPLAINANT

SUBSCRIBED AND SWORN TO BEFORE ME THIS DATE
(*month, day, year*)

CHARGE OF DISCRIMINATION

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and EEOC

State or local Agency, if any

THE PARTICULARS ARE *(If additional paper is needed, attach extra sheet(s))*:

See attached Narrative.

I want this charge filed with both the EEOC and the State or local Agency, if any. I will advise the agencies if I change my address or phone number and I will cooperate fully with them in the processing of my charge in accordance with their procedures.

I declare under penalty of perjury that the above is true and correct.

11-22-2021
Date

Charging Party Signature

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I swear or affirm that I have read the above charge and that it is true to the best of my knowledge, information and belief.

SIGNATURE OF COMPLAINANT

SUBSCRIBED AND SWORN TO BEFORE ME THIS DATE
(month, day, year)

PRIVACY ACT STATEMENT: Under the Privacy Act of 1974, Pub. Law 93-579, authority to request personal data and its uses are:

1. FORM NUMBER/TITLE/DATE. EEOC Form 5, Charge of Discrimination (11/09).

2. AUTHORITY. 42 U.S.C. 2000e-5(b), 29 U.S.C. 211, 29 U.S.C. 626, 42 U.S.C. 12117, 42 U.S.C. 2000ff-6.

3. PRINCIPAL PURPOSES. The purposes of a charge, taken on this form or otherwise reduced to writing (whether later recorded on this form or not) are, as applicable under the EEOC anti-discrimination statutes (EEOC statutes), to preserve private suit rights under the EEOC statutes, to invoke the EEOC's jurisdiction and, where dual-filing or referral arrangements exist, to begin state or local proceedings.

4. ROUTINE USES. This form is used to provide facts that may establish the existence of matters covered by the EEOC statutes (and as applicable, other federal, state or local laws). Information given will be used by staff to guide its mediation and investigation efforts and, as applicable, to determine, conciliate and litigate claims of unlawful discrimination. This form may be presented to or disclosed to other federal, state or local agencies as appropriate or necessary in carrying out EEOC's functions. A copy of this charge will ordinarily be sent to the respondent organization against which the charge is made.

5. WHETHER DISCLOSURE IS MANDATORY; EFFECT OF NOT GIVING INFORMATION. Charges must be reduced to writing and should identify the charging party and respondent and the actions or policies complained of. Without a written charge, EEOC will ordinarily not act on the complaint. Charges under Title VII, ADA or GINA must be sworn to or affirmed (either by using this form or by presenting a notarized statement or unsworn declaration under penalty of perjury); charges under the ADEA should ordinarily be signed. Charges may be clarified or amplified later by amendment. It is not mandatory that this form be used to make a charge.

NOTICE OF RIGHT TO REQUEST SUBSTANTIAL WEIGHT REVIEW

Charges filed at a state or local Fair Employment Practices Agency (FEPA) that dual-files charges with EEOC will ordinarily be handled first by the FEPA. Some charges filed at EEOC may also be first handled by a FEPA under worksharing agreements. You will be told which agency will handle your charge. When the FEPA is the first to handle the charge, it will notify you of its final resolution of the matter. Then, if you wish EEOC to give Substantial Weight Review to the FEPA's final findings, you must ask us in writing to do so within 15 days of your receipt of its findings. Otherwise, we will ordinarily adopt the FEPA's finding and close our file on the charge.

NOTICE OF NON-RETALIATION REQUIREMENTS

Please **notify** EEOC or the state or local agency where you filed your charge **if retaliation is taken against you or others** who oppose discrimination or cooperate in any investigation or lawsuit concerning this charge. Under Section 704(a) of Title VII, Section 4(d) of the ADEA, Section 503(a) of the ADA and Section 207(f) of GINA, it is unlawful for an *employer* to discriminate against present or former employees or job applicants, for an *employment agency* to discriminate against anyone, or for a *union* to discriminate against its members or membership applicants, because they have opposed any practice made unlawful by the statutes, or because they have made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under the laws. The Equal Pay Act has similar provisions and Section 503(b) of the ADA prohibits coercion, intimidation, threats or interference with anyone for exercising or enjoying, or aiding or encouraging others in their exercise or enjoyment of, rights under the Act.

EEOC CHARGE NARRATIVE

FOR

DAVID PLATTA

PLATTA V. GRAY TELEVISION, INC.

2021-11-22

Mr. David Platta ("Mr. Platta"), until recently, was the well-known and beloved 62-year-old Sports Director for WTVM, a Gray Television, Inc. company in Columbus, Georgia ("Gray"). After an incredible *36 years* of loyal and stellar service to Gray, effective September 15, 2021, Mr. Platta was abruptly terminated by Gray when he could not, on religious grounds, be coerced by threat of job loss into accepting the experimental and unapproved COVID-19 vaccine—known to contain aborted human fetal cells--that Gray mandated for all its employees. As a direct result of his sincerely held religious beliefs, which Gray failed and refused to accommodate, he was forced out of the Company in the most professionally humiliating and illegal manner. This unceremonious forced expulsion was despite his three-year employment contract--which provides for continued employment through **September 3, *2023***. See Exhibit A. Apparently, his exercise of his religious beliefs by refusing the fetal-cell-laden vaccine and maintaining his physical body's integrity[1], was baselessly and outrageously characterized by Gray as "gross misconduct" in an attempt to escape the requirements of his employment contract.

The significant facts, circumstances and legal issues are presented below.[2]

I. Gray Breached Its Contract with Mr. Platta.

Mr. Platta had a written contract of employment with Gray for a defined period of three years, from September 3, 2020, through September 2, 2023. See Exhibit A. There is no question Mr. Platta did nothing to breach his contract. Under any sane definition, gross misconduct or even a policy violation is not established by exercising one's religious rights under Title VII and the U.S. Constitution, among other laws, nor is it "gross misconduct" to decline an experimental,

[1] In the Christian belief system, the physical body is considered the Temple of God and is not to be desecrated. For perspective on the Christian (Catholic) view of being forced to take the experimental and insufficiently tested COVID-19 vaccine, see the excellent Letter #136, 2021, Wed, Oct 27: Archbishop Viganò's Open Letter to Archbishop Gomez and excepts from same, attached as Exhibit B.

[2] This letter should not be construed to detail *all* the relevant facts and circumstances, or all the legal issues applicable to Mr. Platta's situation. We reserve the right to add facts, legal issues and claims regarding this matter at any time as our investigation continues.

unapproved, ineffective, morally reprehensible, hazardous, and unnecessary "vaccine"[3]. To demand that he allow a syringe containing human fetal cells, to puncture his skin and physically fire into his body the religiously- despicable fluid is morally reprehensible to say the least, and also violates a plethora of other laws. In fact, the very demand that he submit to this invasive procedure by those with no medical degree or training, and without regard to or knowledge of his particular medical circumstances, raises numerous additional legal and ethical issues in addition to religious discrimination, including, without limitation, Constitutional issues of bodily integrity, personal choice, the Constitutional right to privacy, right to medical privacy, an individual's right to choose his medical treatments, the doctrine of informed consent, and even the tort of assault and battery.

For the EEOC's purposes, the vaccine mandate itself and Gray's characterization of Mr. Platta's refusal of it on religious grounds as "gross misconduct," is nothing short of harassment and discrimination in violation of Title VII. Mr. Platta knows of no other contract employees characterized as engaging in "gross misconduct" for refusing the vaccine, although it is possible Gray has engaged in discrimination and harassment of all employees refusing to take the vaccine on religious grounds by denying their requests for accommodations across the board and then terminating them without basis and without interactive discussion.

Gray has recognized in its own policy documents that it may not enforce a policy that precludes or dissuades employees from engaging in activities or conduct protected by federal, state, or local law. Given the actions Gray has taken with regard to the vaccine mandate and refusing religious accommodations, such alleged policy declarations mean nothing—they are with respect to the vaccine mandate and religious exemptions, a mere ruse to infer the appearance of lawfulness. The EEOC should immediate request from Gray evidence of all the religious exemptions and accommodations it has granted in response to the vaccine mandate. What is no doubt an extremely paltry number, if any, will demonstrate the reality of this ruse.

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[3]This liquid is not even a vaccine in the traditional sense. Rather, in order to attempt to distribute it to the entire world, to the tune of literally billions of dollars so far, plus profits from treatment of the many side effects the shot causes, the very definition of a vaccine was changed to accommodate this new, invasive, untried, untested technology, which has caused the death of an estimated 45,000 people. See, e.g., https://www.lowerdrugpricesnow.org/wp-content/uploads/LDPN_Pandemic_Profiteering_REPORT-FINAL.pdf; https://renz-law.com/wp-content/uploads/Jane-Doe-Declaration.pdf;http://indepthnh.org/wp-content/uploads/2021/10/COVID-Report-from-Rep.-Weyler-3.pdf (The Vaccine Death Report)

While there are many legal, moral, ethical, and religious issues that could be here discussed, at this time only the most blatant violations of law will be addressed.[4]

In addition to other damages for the discrimination and harassment he has suffered, Mr. Platta is entitled to the entire value of the salary and benefits due under his three-year contract, including any bonuses he would naturally have received (consistent, at a minimum, with those he has received for similar performance or circumstances in a similar time period in the past) from his Company-inflicted termination date of September 15, 2021 through the Company's and Mr. Platta's agreed upon contractual termination date of September 3, **2023**. Just in salary alone, we calculate this to be not less than **$180, 298.00 plus interest.** He is also entitled to the value of all benefits, bonuses, awards, financial incentives, retirement contributions and other compensation of any kind that he would have received, had Gray not discriminated against him and thereby breached its employment agreement with him. Moreover, since the Company breached its contract with Mr. Platta, he is relieved from any and all obligations he would have otherwise had under the contract, including without limitation, its noncompete provisions. See, e.g., Chaudhun v. Fannin Regional Hospital, Inc., 317 Ga. App. 184 (2012).

II. Gray Unlawfully Failed to Accommodate Mr. Platta's Sincerely Held Religious Beliefs.

A. Gray failed and refused to have the required Interactive Discussion and Ignored Mr. Platta's Important Religious Accommodation Questions.

In connection with notice of the vaccine mandate Gray planned to impose, Mr. Platta in a timely fashion provided a detailed, sincere, religious objection, and completed fully the Religious Accommodation Form provided by Gray ("Request"). See Exhibit C. Although Mr. Platta had many questions about the mandated vaccine, and verbally and in writing sought an information exchange as part of an interactive discussion required by law about the vaccine mandate and a religious accommodation to same, his questions were ignored. This is in spite of the clear interactive discussion mandate, recognized by legal authority and Gray itself as very important.[5] On the Gray Religious Accommodation Form ("RAF"), it states:

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[4] Should resolution of this matter not be forthcoming, all legal issues will be addressed in the appropriate forum.

[5] See Thomas v. National Ass'n of Letter Carriers, 225 F.3d 1149 (10th Cir. 2000), explaining: "This [religious accommodation] statutory and regulatory framework, like the statutory and

> Upon receipt of your completed form, **Corporate HR will contact you** as soon as practicable t**o discuss your accommodation request, clarify your needs, and, if necessary, request and/or gather additional information from you. It is important that the Company and you engage in this interactive process.** Please respond promptly to any communications you receive from Corporate HR relating to your request.

See Exhibit C. Despite the bolded language above and other representations from Gray that discussion would be forthcoming, no such discussion took place. Gray chose not to even discuss with Mr. Platta the extremely reasonable, well-reasoned and well-supported accommodation he offered, which would have caused zero cost or hardship to Gray and its employees.

B. Mr. Platta Explained His Religious and Moral Concerns and Offered a Reasonable Accommodation, But His Concern and Request Fell on Deaf Ears.

Mr. Platta politely and articulately explained his religious and moral concerns and offered a reasonable accommodation that would have allowed him to comply with his religious beliefs, ethics, and morals, and simultaneously would have caused Gray zero hardship. See Exhibit C. But Mr. Platta received no meaningful response to his supplied information or the reasons for his Request. Instead, his Request was flatly denied with no discussion via an impersonal email to "Dear Supervisor," saying only that his job required "close contact with other individuals.[6]"

1. Granting His Request Would Not Have Caused Gray any Undue Hardship.

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regulatory framework of the Americans with Disabilities Act (ADA), involves an interactive process that requires participation by both the employer and the employee. See Ansonia Bd. of Educ. v. Philbrook, 479 U.S. 60, 69, 107 S. Ct. 367, 372, 93 L. Ed. 2d 305 (stating that, consistent with the goals expressed in the legislative history of the religious accommodation provision, "courts have noted that ***HN6*** bilateral cooperation is appropriate in the search for an acceptable reconciliation of the needs of the employee's religion and the exigencies [**12] of the employer's business") (internal quotations and citations omitted)."
Thomas, *supra.,* 225 F.3d at, 1155.

[6] See Exhibit D, Email to "Dear Supervisor" from Gray TV-HR Communications dated September 11, 2021 re "Update Regarding Your Vaccination Status."

Recognizing Gray's interest in the protection of other employees, Mr. Platta did significant research and provided for Gray's review science and other websites supporting both his religious beliefs and his accommodation recommendation[7]. Mr. Platta details in his Request an accommodation that assures he would not become a "transmission vehicle" to other employees:

> "There are two other forms of protection that equal or better the vaccines available—natural immunity from recovery from a prior COVID infection[8], and from a prophylactic regimen involving currently available drugs used in combination with supplements.[9]
> I have been prescribed hydroxychloroquine (200 mg) to be taken weekly. In addition, I am taking on a daily basis zinc (50mg), Vitamin D (5000 IU), Vitamin C (700mg) and Quercetin (250mg) as supplements in support. Information on current studies on the efficacy of hydroxychloroquine can be found at https://hcqmeta.com/#conclusion with other links on that site if you wish to dive deeper into the data.

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[7] As you can see by a review of his completed Religious Accommodation Request Form, Exhibit C, Mr. Platta thoroughly researched the issues and directed Gray to the following websites in support of his religious beliefs and his requested accommodation. It appears no one at Gray actually looked them up in connection with his Request (which appears probable in the circumstances), they are listed below for ease of access and review:

1…https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html
2… https://www.usccb.org/moral-considerations-covid-vaccines
3…. https://blogs.sciencemag.org/pipeline/archives/2021/05/04/spike-protein-behavior
4…. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
5…. https://www.ahajournals.org/doi/full/10.1161/CIRCRESAHA.121.318902
6….https://www.contagionlive.com/view/spike-protein-of-sars-cov-2-virus-alone-can-cause-damage-to-lungs
7.....https://podcasts.apple.com/us/podcast/how-to-save-the-world-in-three-easy-steps/id1471581521?i=1000525032595

It should be noted that, there is abundantly more information on the internet suggesting that the vaccine is hazardous to one's health and may cause death. See discussion regarding VAERS *infra* and documents referenced in f.n.3. It should further be noted that, under the law, Mr. Platta's sincere religious beliefs are to be considered sacred and protected, and it does not even matter if they agree with any particular organized religion or science. As the EEOC has explained: It is generally inappropriate to question the sincerity of an employee's sincerely held beliefs. See EEOC.gov, Section 12, Religious Discrimination and cases cited therein.

[8] See, e.g., https://www.projectveritas.com/news/pfizer-scientist-your-antibodies-are-probably-better-than-the-vaccination/ (interviews with Pfizer employees admitting that post-COVID infection natural immunity was significantly better that the vaccine.

[9] See Zelenko Protocol, https://vladimirzelenkomd.com/prophylaxis-protocol/.

> I would be more than happy to sign something weekly verifying that I'm following this protocol.
>
> There are other concerns about the safety of the COVID vaccines. Apparently, the S-Protein in the shot is not acting as expected, and instead of winding up in the liver to be eliminated after activating the immune system... it is traveling elsewhere in the body (specifically bone marrow and ovaries) and causing damage, including myocarditis and pericarditis in young men, per the CDC.4.

Mr. Platta went on to explain evidence of vaccine damage potential, apparently unexpected by the developers. Importantly from a religious and moral standpoint, he explained that evidence finds that the S-Protein is affecting the ovaries and reproductive systems of women of childbearing age—a significant problem in the Catholic faith, where the creation of life is sacred. As he explained, "Forcing young people to take this risk by mandating the vaccination when safer alternatives are available and known is unethical, inhumane, and in violation of the Christian faith."

Mr. Platta pointed out, and as is well-established in a great many legal and scientific findings (including, among many others, those discussed in the attached Exhibit E (the Florida Lawsuit[10]), **"[W]e have no idea what the long-term effects [of this vaccine] will be since we only have approximately one year's worth of data."[11]**

It is the Employer's burden to prove that its attempted coercion of an employee to abandon his sincerely held religious beliefs by threatening termination while concurrently refusing to discuss or accept or propose ANY reasonable accommodation was somehow justified. The Employer **must *prove*** in this case that ANY accommodation at all would cause the Employer "undue hardship" and must also somehow justify its failure to engage in any meaningful interactive discussion.[12] Indeed, Gray's burden of proof in the case of this 36-year stellar employee with sincere religious beliefs is a heavy one.

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[10] See Exhibit D, John Doe v. Lloyd Austin et al (Airforce, Navy, FDA, and Army), Civil Action No. 3:21-cv-01211-TKW-HTC (N.D, Fla.) ("Florida Lawsuit") at 9, 31.

[11] In fact, the Vaccine was unleashed on the public as an experimental vaccine after only two months of testing. This is unheard of in the history of ethical testing. See *generally* FDA, Emergency Use Authorization (EUA) for an Unapproved Product: Review Memorandum (Dec. 11, 2020), available at: https://www.fda.gov/media/144416/download.

[12] See generally, Adeyeye v. Heartland Sweeteners, LLC, 721 F.3d 444 (7th Cir. 2013) regarding the Employer's burden in proving undue hardship.

Gray's remarkably harsh termination of Mr. Platta and its breach of a 3-year contract because Mr. Platta would not give up his religious, moral, and ethical convictions is like firing a 36-year stellar Muslin employee, who despite Gray's active and intense coercion to do so, would not eat a ham sandwich. He is exercising his religious beliefs, guaranteed by the U.S. Constitution and Title VII, and he cannot be sanctioned or retaliated against for doing so; a reasonable accommodation must be discussed and made, absent *proven* undue hardship. Religious discrimination and retaliation like that suffered here are flatly against the law. Likewise is Gray's issuance and enforcement of a vaccine mandate and termination of Mr. Platta.[13]

III. Liability should be imposed on Gray for Its Illegal Vaccine Mandate Which, Like a Sledge Hammer, Decimates the Individual Religious Liberties of its Employees .

A. The Recent 5th Circuit Preliminary Injunction Demonstrates In Part the Illegality, Oppression, and Irreparable Injury Gray's Vaccine Mandate has on Mr. Platta's and Other Employees' Religious Liberty.

In its recent November 12, 2021 holding, the 5th Circuit Court of Appeals in BST Holdings, LLC et al v. OSHA, attached as Exhibit F, the court granted plaintiffs' preliminary injunction staying OSHA's "staggeringly overbroad" attempted Vaccine Mandate for all employers over 100 employees, insisting the Mandate must be immediately halted. Recognizing the substantial burden and irreparable injury individual employees suffer when "put to a choice between their jobs(s) and their jab(s)," the court declared that the loss of constitutional freedoms [which would include loss of religious freedoms guaranteed by the U.S. Constitution and Title VII] "for even minimal periods of time…unquestionably constitutes irreparable injury," citing

[13] More and more government figures, courts, companies, and others are recognizing the illegality of vaccine mandates and the safety and efficacy issues with the vaccines. See, e.g., Alabama Governor Kay Ivey's Executive Order No. 724 addressing the "illegal overreach" of the vaccine mandate dated Oct. 25, 2021; See also, https://www.fiercepharma.com/pharma/fda-says-label-warning-coming-for-heart-inflammation-pfizer-bnt-moderna-covid-19-vaccines; David J. Sorensen and Dr. V. Zelenko, The Vaccine Death Report, September 2021, found at http://indepthnh.org/wp-content/uploads/2021/10/COVID-Report-from-Rep.-Weyler-3.pdf. See also the recent holding by the 5th Circuit Court of Appeals in BST Holdings, LLC et al v. OSHA, where the court granted plaintiffs' preliminary injuction, while recognizing the substantial burden and irreparable injury individual employees suffer when "put to a choice between their jobs(s) and their jab(s)."

Elrod v. Burns, 427 U.S. 347, 373 (1976). Here, Gray, by its vaccine mandate has slaughtered the religious freedom of Mr. Platta and a multitude of others at Gray. The EEOC should immediately obtain evidence from Gray regarding how many religious objections and requests for accommodations were made by employees, and how many such requests Gray granted or denied. If such evidence shows that few if any religious objections were given credence by Gray, this pattern and practice loudly demonstrates an indifference to the law, and specifically to the rights of Gray employee to object to the vaccine mandate on religious grounds and be provided a reasonable accommodation. While multitudes of large entities, both private and government, appear to be "thumbing their noses" at religious rights, it is the mandate of the EEOC to protect those rights and to assure those injured by such legal indifference are made whole.

B. The Christian Religion Prohibits Intentionally Desecrating the Human Body by Injection of A Vaccine Known to Cause Harm, as The Body is the Temple of God.[14]

As Archbishop Vigano explained in his Letter, Exhibit B, **"** Having established that the drugs sold as vaccines do not give any significant benefit and on the contrary may cause a very high percentage of deaths or grave pathologies[11] even in subjects for whom Covid does not represent a threat,[12] I do not think that we can conclude that there is any proportionality between the potential damages and the potential benefits.

"This means therefore that there is a **grave moral obligation to refuse inoculation** as a possible and proximate cause of permanent damages[13] or death. In the absence of benefits, there is therefore no need to expose oneself to the risks of its administration, but on the contrary **there is a duty to refuse it categorically.**

C. The Law Upholds Religious Freedom in that it Mandates a Right to Choose Whether to Have the Vaccine or Not.

1. <u>The Law Holds An Experiment Vaccine Licensed Only Under an EUA Must Be Voluntary. Everyone Has the Right to Informed Consent.</u>

[14] 1 Corin 6:19-20. "….(D)o you not know that your body is the temple of the Holy Spirit who is in you, whom you have from God, and you are not your own? For you were bought with a price; therefore glorify God in your body and in your spirit, which are God's."

As stated, the mandating of the Covid-19 vaccination whether by a private employer or by the government is a violation of multiple laws. According to law, including the Doctrine of Informed Consent among multiple others, all employees must be advised that they have the *right to refuse* to take any COVID-19 vaccine, especially since it is still an experimental vaccine, and only licensed under Emergency Use Authorization (EUA) by the FDA. Any other action is contrary to federal and other laws and Constitutional rights.

Despite the ongoing mantra found in CDC and FDA materials that the vaccine is "safe and effective," research is plentiful that demonstrates that it is neither safe nor effective, and Mr. Platta has been gravely injured not only by Gray's callous disregard of his religious beliefs, which is intertwined with Gray's preclusion of his right to informed consent, but also by its negligence in failing to do adequate research before *making its own representations* that the vaccines are "safe and effective."

A careful examination of the FDA actions, or even just a reading of Mr. Platta's Religious Accommodation Request and the data cited therein, would have revealed to Gray that, despite the "safe and effective" vaccine mantra that is attempted to be indoctrinated everywhere by the Big Pharma-influenced FDA and CDC, the only vaccine available to anyone in United States is and has always been highly experimental and thus cannot appropriately be labeled "safe and effective." There is no rational basis, after a mere two months of testing,[15] to repeatedly and loudly claim that this vaccine is "safe and effective," especially when the normal testing time is always a matter of years--not months. This kind of irrational conduct on the part of government agencies charged with protecting U.S. citizens from dangerous drugs and treatments is frankly unheard of in FDA or CDC history. Further, and incomprehensibly, its rush to market and massive media campaign is purportedly to combat a virus that most people have an over 98% chance of surviving.[16]

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[15] See Florida Lawsuit at 31, n. 39 citing FDA, Emergency Use Authorization (EUA) for an Unapproved Product: Review Memorandum (Dec. 11, 2020) at https://fda.gov/media/144416/download (last visited Oct 1, 2021).

[16] See WebMD.com, reporting a COVID survival rate of between 97% and 99.75%. Compare it to CDC death by flu numbers and other mortality numbers. Evan a cursory review of CDC death numbers over the past several years show that the total number of deaths from all causes have not changed much. There is no evidence that COVID 19 has reduced the population significantly. However, there is evidence that the dangers posed by the vaccine have killed in the neighborhood of 45,000. See Declaration of Jane Doe, supra., and CDC's VAERS information generally. It is widely reputed that hospitals were paid millions of dollars to characterize any

The fact is this: There is no "approved" vaccine available to Mr. Platta or anyone else in the United States, even if desired and not against religious convictions.

2. <u>All vaccines available in the United States are Experimental, and thus require informed Consent.</u>

While one may think that the Comirnaty vaccine was "FDA Approved," and thus vaccine mandates could now be allowed in the United States, this conclusion would be erroneous.

3. <u>The FDA "Approval" of The Pfizer Vaccine Comirnaty did *Not* Authorize a Vaccine Mandate.</u>

Looking at the FDA approval of the Pfizer vaccine, one can see the that official Biologics License Application (BLA) Approval clearly states that Pfizer is to "*label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials*". Also, on the FDA's "Summary Basis for Regulatory Action" document, it clearly states

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death possible as a COVID death to drive up fear and increase demand for the vaccine. There is now significant evidence that the number of actual COVID deaths is highly inflated, as now admitted by hospitals. See, e.g., YouTube Video Statement of Senator Scott Jensen in "Attacked by Minnesota Medical Board" dated 7/6/20. No vaccine in the history of the world has been allowed to kill so many people and remain on the shelves. Yet, the current vaccines not only remain on the shelves, but they are also attempted to be mandated and pushed by government officials and now even private employers by unprecedented enticement or threat. Reportedly, Pfizer has already made over 89 billion dollars from the sale of the vaccine and stands to make much more in the treatment of the adverse medical conditions the vaccine has caused. Additionally, now that it has been proven that the vaccine is ineffective in warding off COVID-19, booster upon booster, at tremendous profit to the pharmaceutical companies, will now be "recommended." See. e.g., cnbc.com, "Moderna Releases New Data on Covid Breakthroughs It Says Supports Need for Booster Shots." And the chance of dying from a complication of the vaccine is significantly higher than the risk of catching COVID-19 and dying. For example, General Colin Powell, who was fully vaccinated, reportedly died of "COVID complications." See nbcnews.com. Israel, whose population is almost fully vaccinated, has had a high rate of "breakthrough" cases of COVID and resulting adverse medical consequences and deaths, easily demonstrating the limited efficacy of the $89B vaccine and further establishing the risk of the vaccine. See also, Exhibit B. Astonishingly, apparently to quiet the truth, "OSHA has advised Employers Not to Record Adverse Reactions from **Voluntary** COVID-19 Vaccines on the OSHA 300 Log." See Seyfarth Shaw LLP article of same name by Brent I. Clark, et al dated 4/23/21, summarizing OSHA regulations and guidance. Adverse reactions from **mandated** vaccines are still required to be recorded. But Seyfarth seems to infer ways of avoiding that obligation.

that the approval is designated for the proprietary name "*Comirnaty*". The FDA also provides that a copy of the "*Comirnaty*" insert that is to be placed in each vaccine package.

One of the issues at hand is that no vaccine labeled or packaged as "*Comirnaty*" is available to the American public at this time. The only Pfizer shot available to the American public at this time is labeled "*BioNTech*" which is, according to Pfizer's and FDA's websites, still under Emergency Use Authorization (EUA). The FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances … **That they have the option to accept or refuse the (EUA) product** …" [17]

Confusion arises because the FDA, in an apparently improper attempt to facilitate or encourage mass vaccine mandates, made the erroneous statement that the BioNTech vaccine could be used "interchangeably" with the Comirnaty vaccine. See Exhibit G, FDA Approval Letter dated 2021-08-23. See also Exhibit E, Florida Lawsuit, pages 3-4, 26-37 (explaining that, legally, one cannot substitute, or use interchangeably, an approved vaccine and an experimental vaccine.) The two classes are legally distinct, as the FDA admits.[18] Approved vaccines and EUA vaccines undergo different processes, and one cannot be substituted for the other.[19] The FDA Approval letter is clear that the EUA (Emergency Use Authorization) status still applies to the Pfizer-BioNTech COVID 19—i.e., the only Pfizer vaccine available in the United States.

4. **VAERS, Among Many Other Reports, Demonstrates That The Vaccine Has Significant Risks That Gray Has No Business Forcing People To Accept.**

The Vaccine Adverse Event Reporting System (VAERS), established in 1990 and co-managed by the CDC and FDA to be the National early warning system responsible for detecting possible safety problems with U.S. licensed Vaccines, has demonstrated the experimental Covid-19 Vaccine is already the deadliest vaccine in its history. According to VAERS[20], there has

[17] See https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained; See also, The Florida Lawsuit attached as Exhibit E, p. 9-10; 21 USC 360bbb3(e)(1)(A)(ii)(III).

[18] See Exhibit G, n. 8, in which the FDA (via Chief Scientist, Denise M. Hinton) admits and approved vaccine (Comirity) and an EUA (BioNTech) are "legally distinct."

[19] See Exhibit E, the Florida lawsuit, at 26-37, which explains this further.

[20] This data was accurate as of the time the research for this letter was originally conducted...By the time this letter is read, the VAERS number of deaths is no doubt appreciably higher, as more and more have succumbed to the illegal vaccine mandate for fear of losing their jobs and

already been more Life-Threatening events from The Covid-19 Vaccine (14,593 from December of 2020 to 9/2/21), than ALL OTHER VACCINES COMBINED SINCE 1990 (13,579). It also reveals that the Covid-19 Vaccine has already reported near double the number of DEATHS (14,506) from December of 2020 to 9/3/21—more than ALL OTHER VACCINCES COMBINED SINCE 1990 (8,993).[21] This vaccine is also reported to have almost 3.4 times the number of birth defects after vaccination than all other vaccines combined since VAERS inception in 1990.

It violates Mr. Platta's sincerely held religious beliefs to inject such a dangerous "vaccine" into his physical body, or to stand by and allow the physical bodies of others to be impaired, as the body is the Holy Temple of God.

5. Gray Has Mandated an Experimental Vaccine Without Obtaining or Providing the Opportunity for Legally Required Informed Consent.

Thus, what Gray has done by issuing a vaccine mandate, in addition to violating the religious rights of Mr. Platta and others claiming religious exemption, is to *require* everyone in the company to be vaccinated with a demonstrably life-threatening *experimental* (EUA) vaccine or *be fired.* And by this coercive demand, Gray forced a 36-year career veteran to lose his job, career, and livelihood at the age of 62. And that is just one case. Gray has violated the law because, among other things, ***EUA Vaccines, by law, require voluntary, informed consent.***

Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), 21 CFR 360bbb-3 vests the Secretary of Health and Human Services with the permissive authority to grant EUAs provided that appropriate conditions designed to ensure that individuals to whom the product is administered are informed:

1. that the Secretary has authorized the emergency use of the product;

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livelihood. Vaccine mandates have put employees in the untenable position of risking death or severely adverse medical consequences or risking severe financial survival consequences via loss of their employment. This is both overreaching and outrageous. See Executive Order 724 by Governor of Alabama, *supra*. See also Exhibit F, 5th Circuit Opinion, BST Holdings v. OSHA.

[21] See http://vaersanalysis.info/2021/10/01/vaers-summary-for-covid-19-vaccines-through-9-24-2021 for updated data.

2. of the significant known and **potential benefits and risks** of such use, **and** of the extent to which such **benefits and risks** are **unknown**; and

3. **of the option to accept or refuse administration of the product;** of the consequences, if any, of refusing administration of the product; and of the alternatives to the product that are available and of their benefits and risks.

Also **very importantly**, see, 21 CFR 50.25, **Elements Of Informed Consent**, explaining that every person offered an EUA vaccine **must** be given:

(a)(8) **A statement that participation is voluntary,** that refusal to participate **will involve no penalty or loss** of benefits to which the subject is otherwise entitled, and that the s**ubject may discontinue participation** at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure **may involve risks to the subject (or to the embryo or fetus**, if the subject is or may become pregnant) **which are currently unforeseeable.**

Please note that all Covid-19 or Sars-CoV-2 Testing devices and kits are also EUA products and therefore fall under the same requirements outlined in Section 360bbb-3. **Recipients must have the option to refuse administration of any (EUA) product, whether that product is offered by the government or a private employer.**[22]

6. The Nuremberg Code, and Laws Emanating from Same, Made Certain Persons Participating in Medical Experimentation Do So Voluntarily and While Fully Informed of the Risks.

The right to avoid the imposition of human experimentation is fundamental and long-standing. Rooted in the Nuremberg Code of 1947, it has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations.[23] In addition to

[22] See Greg Glaser, Esq. et al, Under Federal Law, Can Your Employer Make You Get the COVID Vaccine? dated 1/29/21, available at https://childrenshealthdefense.org/defender/under-federal-law-can-your=employer-make-you-get-covid-vaccine/.
[23] See e.g., 21 CFR 50.25

the United States regarding itself as bound by these provisions, these principles were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. [24] Simply put, it is unlawful to conduct medical research, even in the case of an emergency, unless steps are taken to secure **informed consent** of all participants. Informed consent here is virtually impossible to obtain, since no one knows the effects, risks, or even the efficacy of these vaccines, given the very, very short two-month testing period before these tests were unleashed onto the masses, pursuant to an EUA.[25] Never before in history has a vaccine or other medical treatment been thrust upon the public with such little testing. Routinely, pursuant to the illegal vaccine mandate issued by Gray and others to coerce people to take the vaccine, hundreds of thousands of human beings have been injected with a substance which is both unknown and unknowable, to the severe detriment of a great many.[26]

This "vaccine" is indeed still in the experimental stages as evidenced by the official FDA "Summary Basis for Regulatory Action" of *Comirnaty* on page 28. Listed on page 28 are a series of ongoing studies including "*Study C4591021*" that evaluates the "*occurrence of myocarditis and pericarditis following administration of COMIRNATY*." That particular study will not be complete until March 31, 2024. Other studies, like "*Study C4591036,*" will not be complete until December 31, 2026.[27] Notably, According to **The Encyclopedia of Genocide and Crimes Against Humanity**, Macmillan Reference, 2004, pp. 669-675 *"Medical experimentation refers*

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[24] See regulatory provisions cited *supra*.

[25] Moreover, doctors, employers, and employees are almost always ignorant of the vaccine's contents as a great many of the vaccine boxes supplied to providers have intentionally "blank" medical inserts. These inserts are supposed to list the drug's ingredients, indications, contraindications, and other hazards. The purported, and noncredible, reason for having a blank insert is because "the box itself guides users to details on the FDA's emergency use authorization for the vaccine and updated fact sheets." Specifically, it has a QR code used to direct the recipient who has a smart phone and time to look to a website. See https://www.usatoday.com/story/news/factcheck/2021/05/20/fact-check-blank-insert-j-j-vaccine-has-instructions-information-online/5057848001/. It can be guaranteed that many fewer people will go to the trouble of looking up a QR Code than would have just read the insert. With regard to a vaccine where there is much controversy regarding contraindications, and much pressure to just take the vaccine no matter what, this packaging decision seems highly suspect. They could have put the information *and* the QR code on the insert, with appropriate instruction to check the web for more and up-to-date information.

[26] See VAERS; see also, David J. Sorensen and Dr. V. Zelenko, The Vaccine Death Report, September 2021, found at http://indepthnh.org/wp-content/uploads/2021/10/COVID-Report-from-Rep.-Weyler-3.pdf

[27] See also https://www.fiercepharma.com/pharma/fda-says-label-warning-coming-for-heart-inflammation-pfizer-bnt-moderna-covid-19-vaccines re warning expected from FDA.

to the testing and evaluation of a new drug or procedure on a human person in order gain generalizable knowledge that can be used for various purposes". According to the **American Heritage Medical Dictionary**, A Medical Experiment is a *"test under controlled conditions that is made to demonstrate a known truth, examine the validity of a hypothesis, or determine the efficacy of something previously untried".*

Through an apparently boundless mass media campaign designed to instill great fear of a virus that has approximately a 98% or better survival rate, and the consequent push to purchase tens of billions of dollars' worth of vaccine (so far),[28] America and the World have become the Experimental Laboratory for this Vaccine, and its people have become Lab Rats—the ability to provide informed consent has been routinely withheld, as employers and government and even the President are purporting to "mandate" the vaccine, and thus strip the people of the ability to "volunteer," to give informed consent, or even to avoid termination and other horrific consequences where religious or other reasons prohibit them from taking the vaccine. Even in an emergency, however, there is no right to strip an employee of his fundamental rights. [29]

6. All U.S. Citizens Have the Right to Informed Consent, Personal Autonomy and Bodily Integrity

The right to avoid physical harm is fundamental, and employers do not have the authority to put their employees in harm's way, even if they think it would benefit other employees. Nor do they have the right to substitute one type of harm or injury for

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[28] See, e.g., https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-raises-estimates-2021-sales-covid-19-vaccine-335-bln-2021-07-28/.

[29] Government agencies purporting to have an interest in the protection of lives through mass injections of the Vaccines fall short of justifying "*any plenary override*" of "*individual liberty claims*." The Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the *right to* obtain medical intervention. See, e.g., Cruzan v. Director, Mo. Dept of Health, 497 U.S. 261 (1990) ("the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, ….") See also re forced medical treatment: Rochin v. California, 342 U.S. 165, 172(1952) (officers forcibly pumping suspect's stomach for morphine capsules found to "shock the conscience"); Hefferan v. Corda, 498 F. App'x 86, 89 (2d Cir. 2012) (stating that "arbitrary" and "outrageous" Government action satisfies shock the conscience standard). See also, the Florida Lawsuit, Exhibit E. And see 5th Circuit Opinion, which describes the OSHA Vaccine Mandate as exhibiting "grave statutory and Constitutional issues" and a "one-size-fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly ;grave danger' the Mandate purports to address."

another. Those choosing to avoid the risks of the vaccine have as much right to safety as do the those deciding to risk the vaccine. [30] OSHA explains: "Under the OSH Act, employers are responsible for providing a safe and healthy workplace free from recognized hazards likely to cause death or serious physical harm. As information regarding the COVID "pandemic" comes out, more and more evidence is revealed indicating the pandemic was not a naturally occurring phenomena. Mr. Platta, in addition to and as part of his religious exemption—which is absolute—has a more than legitimate concern that the vaccine will cause death or serious physical harm, which is also against his religion, which views all life a precious and a gift from God. Neither the state, nor the federal government, nor Gray can justify an override of individuals rights to life, liberty, the pursuit of happiness, and the right to practice one's religion without fear of retribution. These rights are guaranteed by the Constitution, Title VII, along with the regulations of OSHA, and the EEOC. See especially 21 CFR 25.

The 5th Circuit aptly described a vaccine mandate as exhibiting "grave statutory and Constitutional issues" that acts as a "one-size-fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly 'grave danger' the Mandate purports to address." See Exhibit F.

7. Vaccine Mandates fall short of justifying "*any plenary override*" of "*individual liberty claims.*

Government agencies, and private employers, purporting to have an interest in the protection of lives through mass injections of the Vaccines fall short of justifying "*any plenary override*" of "*individual liberty claims*" including religious liberty claims. The Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the *right to* obtain medical intervention.[31] See also, Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261 (1990), where the U.S. Supreme Court has also recognized the vital liberty interest of persons in refusing unwanted medical treatment

[30] See generally, https://www.osha.gov/workers.
[31] See, e.g., *Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990).*

and to choose medical treatment if they want to: "Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment…."[32] Id., 505 U.S. at 857, See also, Riggins v. Nevada, 504 U.S. 127, 134 (1992), holding that, under the 14th Amendment Due Process Clause:

> The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty" as well as his privacy, and right to bodily integrity.

As in the multiple cases establishing a woman's right to choose an abortion[33], it is everyone's right to choose a medical procedure." It is abhorrent and an abrogation of the rights we have all enjoyed as U.S. citizens for decades now to have an employer, the government or anyone else—not even a doctor—**mandate** a medical procedure. Gray has no qualifications, nor any right, to do so.[34]

This was the law even prior to the development of the Law of Informed Consent, starting in 1914 when Judge (later Supreme Court Justice) Benjamin Cardozo validated the concept of voluntary consent in Schloendorff v. Society of New York Hosp.,105 N.E. 92, 93 (N.Y. 1914) when he deemed any medical intervention without Informed Consent an unlawful **trespass**:

> "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an **assault** for which he is liable in damages."[35]

As it pertains to informed consent, a Court as recently as 2013 in the case of Missouri vs McNeely, 569 US 141, 15 (2013) held that even a

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[32] Planned Parenthood of Southeastern Pa. v. Casey, 505 US 833, 857 (1992).

[33] While for religious reasons, Mr. Platta disagrees that all have a right to an abortion under defined circumstances, it nonetheless is the law in the U.S. This law in the context of the vaccine mandate stands for the right to choose what happens to one's own body, and that an individual has a right to choose to have a medical procedure or not.

[34] Albright v. Oliver, 510 U.S. 266, 272 (1994): "[t]he protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity."
Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right . . . to bodily integrity."

[35] Emphasis added.

> "…diminished expectation of privacy does not diminish the… privacy interest in preventing a government agent from piercing the… skin. And though a blood test conducted in a medical setting by trained personnel is less intrusive than other bodily invasions, this Court has never retreated from its recognition that **any compelled *intrusion into the human body implicates significant, constitutionally protected privacy interests…"***

"This notion of bodily integrity has been embodied in the requirement that informed consent is required for medical treatment. The logical corollary of the doctrine of informed consent is that the patient generally possesses *the right not to consent,* that is, to refuse treatment." Cruzan, *supra.*, 497 U.S. at 269.

B. Mr. Platta Has A Liberty Interest, and a Religious Interest, in His Right to Work and Engage in Business Activity Which Should Not Be Taken Away by an Illegally Mandated Vaccine.

This Liberty Interest grated by the U.S. Constitution and applicable case law also relates to Mr. Platta's Christian religious convictions.[36] The 14th Amendment guarantees a citizen's right to work for a living and to support him or herself by pursuing a chosen occupation. Board of Regents v. Roth, 408 U.S. 564, 572 (1972); Truax v. Raich, 239 U.S. 33, 41 (1915) ("It requires no argument to show that the right to work for a living in the common occupations of

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[36] The Christian faith, based on the Holy Bible, supports a person's right to be able to continue his God-given livelihood, which includes the ability to buy, sell and provide for his family. As established by a specific Biblical prophecy, the vaccine mandate contradicts a man's entitlement to work, buy and sell to support his family. Although there are many scriptures that support this religious belief, the following is relevant:

1. Revelation 13:16-17 that gives insight into an Antichrist agenda in the last days that is warned about in the Christian faith:

   > "He causes all, both small and great, rich and poor, free and slave, to receive a mark on their right hand or on their foreheads, and that no one may buy or sell except one who has the mark or the name of the beast, or the number of his name."

2. 1 John 2:18 says, "Little children, it is the last hour; and as you have heard that the Antichrist is coming, even now many antichrists have come, by which we know that it is the last hour."

Christians believe that, before the return of Jesus Christ, the Antichrist agenda will be implemented to force certain things upon people by restricting their ability to buy or sell unless they cooperate and comply with certain mandates. While the vaccination mandate may not be the Mark of the Beast, the vaccination mandate appears to be a precursor to the Mark of the Beast prophesied to come because it restricts a person's ability to buy or sell.

the community is of the very essence of the personal freedom and opportunity that it was the purpose of the [14th] Amendment to secure.").

1. **Businesses are not shielded from liability if they mandate experimental agents.**

Without the right to work in a profession of our own choosing, rather than being directed into a profession by state bureaucrats or being directed not to work and placed on state subsidies, we are slaves. Employers are liable for any conduct, acting under color of law and/or authority of government agencies, that they personally and through their own actions, with deliberate indifference, set the conditions for, or commit, direct, order confirm, ratify, acquiesce to, have command responsibility for, aid and abet, conspire to, and/or otherwise directly or indirectly cause or facilitate. That includes the violations of law set forth herein, which serve to deprive employees clearly established, constitutionally protected liberty interests, i.e., to work in the profession of their own choosing; to practice their religious beliefs; to preserve their physical integrity, and to choose whether or not to have a medical procedure or an experimental vaccine after being informed of its risks in full. Arguably, a reasonable corporation would or should have known that a vaccine mandate was illegal, and that by issuing and enforcing such a mandate, economic, emotional, psychological, and very possibly, physical injury would likely result to employees like Mr. Platta and possibly their spouses, as well. Denial of Mr. Platta's Constitutional right to religious freedom, even for a while, indisputably results in irreparable injury. See Exhibit F.

2. **Pursuant to the ADAAA[37], Employers are required to uphold their employees Right to Medical Privacy.**

Additionally, we have concern that forcing all employees to disclose their private medical status, i.e., whether they have had the vaccine or not, violates their rights to medical privacy. Further, it appears that Gray is *regarding* Mr. Platta, being unvaccinated, as having a disability, and yet is forcing him to disclose this "disability" essentially in public, in violation of the ADAAA. Further, Gray has discriminated against him, and even terminated him, because of this perceived disability—also a violation of the ADAAA. Under the ADAAA, regarding an

[37] American with Disabilities Act (ADA) of 1990, as amended (42 U.S.C. § 12101, *et seq.); See* 42 U.S.C.A. § 12112.

employee has having a disability, even if he in fact does not have one, and taking adverse action against him as a result of this regard, violates the ADAAA. Further, the ADAAA, requires the employer to accommodate the perceived disability.

3. Gray Made Its Own Representations That the Vaccine is "Safe and Effective."

Of additional concern is that Gray distributed multiple letters taking on itself responsibility for assuring its employees that the vaccine was "safe and effective." [38] In reliance on these letters,[39] and in combination with its threat of termination if a vaccine was refused, we anticipate that Gray will be held liable for negligence[40] or worse when its vaccinated employees experience unwanted medical ramifications or death in reliance on these representations. Fortunately, Mr. Platta will not be one of those, as he has offered to take and is taking a well-established medical protocol to thwart COVID, which is known to be safe. See, e.g., Exhibit H, Nebraska Office of Attorney General Opinion on Ivermectin or Hydroxychloroquine as Off-Label Medicines for the Prevention or Treatment of Covid-19, dated October 14, 2021.

What happens today and in the next few years will be remembered for decades. The EEOC has opportunity here to establish precedent that will save lives, and uphold God-given freedoms. Gray's action, in imposing a mandatory vaccine apparently under the illusion that President Biden or federal agencies had the power to mandate such a thing, was ill-advised on multiple legal grounds. The Nuremberg Trials were notably infamous for the "*Nuremberg Defense*" or the "*just following orders*" defense, which was a plea in a court of law arguing that a person, whether a member of the military, law enforcement, a firefighting force, or the Civilian population, should not be considered guilty of committing actions that were ordered by a governing authority, superior officer or official. As a result, **Nuremberg Principle IV** was established: "*The fact that a person acted pursuant to order of his government or of a superior does not relieve him from responsibility under international law, provided a moral choice was in*

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[38] E.g., on July 27, Gray sent a message to the "Gray Team" stating that, "we know that vaccines are safe and effective against serious symptoms resulting from the coronavirus while the side effects are minor and, in any event, much less risky than actually contracting COVID-19. As you all know, virtually everyone dying from COVID-19 today has not been vaccinated."

[39] Employees had a right to expect that a large employer like Gray would have thoroughly researched these vaccines before forcing them on its employees.

[40] Negligence cases carry with them the potential for compensatory damages, punitive damages, attorney fees, and loss of consortium claims by the spouses of those injured.

fact possible to him." The tribunal sentenced seven of the Nuremberg doctors to death and the remaining eight to life in prison. Aiders and abettors of Nuremberg Crimes are equally guilty and have also been prosecuted, convicted, and executed.

Under the 2005 PREP Act enacted by Congress in 2005, pharmaceutical companies that manufacture EUA vaccines are shielded from liability related to injuries and damages caused by their experimental agents. However, any employer, public school, or any other entity or person who mandates experimental vaccines on any human being is *not* protected from liability for any resulting harm. While vaccine manufacturers may be shielded from liability, Gray is not protected.

Gray's illegal and/or irresponsible mandate of EUA medical products on employees, such as the experimental Covid-19 vaccine, and its forcing, threatening, and otherwise coercing medical treatments on human beings as a condition of employment, is illegal and justifies legal action by the EEOC. Both the company and those individuals making that decision should be held personally liable. We urge the EEOC to take swift action to make Gray comply with the FD&C Act and the terms of the EUA and its accompanying Fact Sheet, advise all employees of their right to accept or refuse any Covid-19 vaccine or Covid testing kits, and withdraw any mandate previously issued. Based on our investigation, any other course of action is contrary to federal law and violates, among other rights, the religious beliefs of Mr. Platta, and likely many others.

Given the current world political and legal climate, should litigation be necessary to resolve these issues, the gravity of Gray's actions would be laid out before the world. We hope the EEOC will act urgently to ensure Gray and other companies respect their employees' medical privacy, religious beliefs, their right to accommodation, and other civil rights Gray's employees are legally owed and deserve as human beings. The EEOC has the authority to rectify the serious harm Gray has illegally thrust upon Mr. Platta, and Mr. Platta urges in immediate thorough investigation of this matter. We hope the EEOC will see the value in acting expeditiously in this regard.

IV. Conclusion

Mr. Platta has suffered significant and irreparable damages as a result of Gray's failure to accommodate his sincerely held religious beliefs, its resulting breach of his employment contract, discrimination and harassment against him on the basis of a regarded disability as well as for requesting religious accommodation, and the consequent termination of the lifelong career of this 36-year veteran employee, whose performance and loyalty was nothing short of

exemplary. Gray failed to have the good faith interactive discussion with Mr. Platta required by law and rejected out of hand his requested religious accommodation without meaningful consideration or discussion regarding his concerns or even his proposed accommodations. Further, Gray presented Mr. Platta with no evidence whatsoever that his requested accommodation would cause an undue burden on or hardship to the company, or any burden at all. Gray failed to even suggest that is suggested accommodations were in some way unsuitable.

Mr. Platta deserves to recover the full extent of his damages in this matter. We urge the EEOC to take action to ensure Mr. Platta's protected rights are vindicated, and that he is made whole.

Sincerely,
HIPES LAW LLC

Jeanne Bynum Hipes
Managing Trial Counsel
Attorney for David Platta

Exhibit Enclosures as stated and referenced on the attached Exhibit List.

C. Additional Resources.

Additionally, you may be interested in the following information:

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[1] https://www.fda.gov/media/97321/download FDA Guidance for Products under EUA

[2] 21 CFR § 50.24 and 21 CFR §50.25

[3] 18 US Code §242 & §241

[4] https://childrenshealthdefense.org/defender/under-federal-law-can-your-employer-make-you-get-covid-vaccine/

[5] https://www.fda.gov/media/151710/download Official FDA BLA Approval of *Comirnaty*

[6] https://www.fda.gov/media/151733/download Summary Basis for Regulatory Action of *Comirnaty*

[7] https://www.fda.gov/media/151707/download *Comirnaty* Package Insert

[8] https://www.law.cornell.edu/uscode/text/18/242

[9] https://history.nih.gov/display/history/Nuremberg+Code

[10] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[11] https://vaersanalysis.info/2021/09/10/vaers-summary-for-covid-19-vaccines-through-9-03-2021/

[12] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

EXHIBITS TO

DAVID PLATTA EEOC CHARGE NARRATIVE

EXHIBIT

A. Platta Employment Contract with Gray

B. Vigano Letter explaining religious issues with Vaccine Mandate

C. Platta Religious Accommodation Request Form Completed

D. Email to "Dear Supervisor" from Gray TV-HR Communications dated September 11, 2021 re "Update Regarding Your Vaccination Status."

E. The Florida Lawsuit.

F. BST Holdings LLC et al v. OSHA (5TH Cir. Nov. 12, 2021)

G. FDA Approval Letter dated 2021-08-23.

H. Nebraska Office of Attorney General Resp re Ivermectin...

NEWS PERSONNEL EMPLOYMENT AGREEMENT

This Agreement ("Agreement") is made and entered into this 3rd of September, 2020 by and between **Dave Platta** ("Employee") and GRAY MEDIA GROUP, INC. d/b/a **WTVM-TV** ("Employer").

WITNESSETH

WHEREAS, Employer desires to employ Employee upon the terms and subject to the conditions hereinafter set forth, and Employee desires to accept such employment;

NOW, THEREFORE, for and in consideration of the mutual promises, covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

(1) **Employment.** Employee's employment under this Agreement shall commence on: **September 3, 2020.**

(2) **Title**. Employee's initial title will be: **Sports Director**

(3) **Location**. Employee's principal work location will be the business offices of WTVM-TV (the "Station"), currently located at: 1909 Wynnton Road, Columbus, Georgia 31906

(4) **Term**.

(a) Employee's first date of employment will be: **September 3, 2020**.

(b) The period of employment will be from the first date of employment through: September 2, 2023.

(c) During the first 90 days of the Term, Employee will be considered a probationary employee. During the 90-day probationary period, Employer will evaluate your fitness and suitability for Employee's position. Employee's employment may be terminated by Employer during the 90-day probationary period for any reason or no reason and without any explanation. In the event of such termination, Employee shall be entitled to payment of any accrued but unpaid wages as of the time of such termination and shall have no further right to payment (including any severance). **This Section 4(c) does not apply to an individual who has been employed by Employer or an affiliate for more than 90 days immediately preceding the date of this Agreement.**

Employee Initials ____

(d) After the 90-day probationary period, Employee's employment under this Agreement may be terminated by Employer prior to the end of the Initial Term or the Option Period in accordance with Sections 11-13 of Attachment A. After the Term, Employee will remain subject to all provisions of this Agreement that ordinarily survive such termination, including without limitation, Sections 8-10 of Attachment A.

(5) **Compensation**. Subject to the terms and conditions set forth in this Agreement, Employer shall pay and Employee shall accept the following annual compensation for performing Employee's job duties under this Agreement:

For the Term:	$87,290.00/annual -
For the First Option Period:	$89,036.00/annual
For the Second Option Period:	$91,262.00/annual

Employee may be entitled to bonuses and additional compensation set forth on Attachment B. In order to receive any bonus, Employee must be employed on the date that bonuses are paid.

Notwithstanding anything to the contrary herein, Employee will accrue Paid Time Off ("PTO") in a manner consistent with the Company's standard policies.

All compensation payable to Employee pursuant to this Agreement shall be subject to applicable taxes and withholding required under federal, state or local law. Further, it is understood by the parties to this Agreement that, Employee may be required to work on occasion more than eight hours per day or more than forty (40) hours per week. Employee understands that, while Employee's hours may vary from week to week, Employee's weekly salary will not vary because Employee's salary compensates Employee for all hours worked.

(6) **Early Termination Restrictions**. Employee understands and agrees that any breach of the terms of this Agreement including, without limitation, by early termination of the Agreement or failure to comply with the exclusivity provisions, will cause damage to Employer that is difficult to estimate. In addition to any other relief that may be available to Employer (including injunctive relief), in the event that Employee breaches the terms of this Agreement, including without limitation, by early termination of the Agreement or failure to comply with the exclusivity provisions, Employee agrees to reimburse Employer within 10 days following a demand for payment by Employer in an amount equal to: (i) the total amount of any moving expenses paid to or on behalf of Employee by Employer in, plus (ii) four (4) weeks' gross compensation in the event of any breach occurring during the Initial Term, six (6) weeks' gross compensation in the event of any breach occurring during the Option Period or four (4) weeks' gross compensation in the event of any breach occurring during any subsequent renewal period. For purposes of this Agreement, Employee's weekly "gross compensation" shall be equal to Employee's average weekly wage payment calculated based on the payroll records of the Company for the four (4) week

Employee Initials

period preceding the date of the termination of employment including any commissions but excluding any extraordinary payment as determined by the Company.

(7) **Consent to Notification.** Employee hereby consents to notification by the Company to any new employer of Employee (whether Employee is an employee, consultant, independent contractor, director, partner, officer, advisor, executive or manager) about Employee's obligations under this Agreement and delivery by the Company of a copy of this Agreement to any such new employer. Employee agrees and acknowledges that the Company's (or the Company's legal counsel's) notification is proper under the controlling state or federal law and that such notification is not interfering with Employee's relationship with Employee's new employer in any way.

(8) **Entire Agreement**. This Agreement together with the Standard Terms and Conditions set forth in Attachment A set forth the entire agreement between the parties and no promises or representations not expressly set forth in this Agreement shall have any effect, and shall be considered merged and integrated into this Agreement. This Agreement may be amended or modified only by a writing signed by the parties.

IN WITNESS WHEREOF, the parties hereto have executed, or caused their duly authorized representative to execute, this Agreement as of the day and year set forth above.

EMPLOYER:
Gray Media Group, Inc.
d/b/a WTVM-TV

BY: _____

TITLE: VP & GM

EMPLOYEE: _____

Employee Initials _____

ATTACHMENT A
News Personnel Employment Agreement
Standard Terms and Conditions

(1) Duties.

(a) During the Term, Employee shall have such duties as are consistent with Employee's position and shall perform such duties and responsibilities that Employer may, in its sole discretion, assign to Employee (the "Services"). Employee agrees that: (1) Employer has the right to alter Employee's duties and title from time to time, and that (2) Employee's title itself neither confers rights upon Employee nor does it limit, in any way, Employer's discretion to alter Employee's duties.

(b) During the Term, Employee shall not engage in any conduct that could reflect negatively on Employer or its reputation in the community. Employee shall not commercially endorse any product or service, without the prior written approval of Employer.

(c) Employee shall perform and discharge faithfully, diligently and to the best of Employee's ability such duties and responsibilities and shall devote Employee's full-time efforts to the business and affairs of Employer.

(d) At no time during the Term shall Employee own or have any interest in any entity where such ownership may conflict with the full and faithful performance of Employee's duty to Employer, specifically including, but not limited to, any companies that produce or distribute video content, features, syndicated films, records, radio or television programs, or that manage or represent talent.

(2) Work Standard and Compliance with Laws. Employee agrees that Employee will at all times comply with and abide by all terms and conditions of this Agreement and all applicable work policies, procedures and rules as may be issued by Employer, including, without limitation, policies relating to Payola/Plugola. Employee further agrees that Employee shall comply with all federal, state, and local statutes, regulations, and public ordinances governing Employee's work.

(3) Additional Benefits. During the Term, Employer will provide Employee with Employer's standard benefits package for individuals employed in the same or a similar capacity as Employee.

(4) Exclusivity of Performance.

(a) Employee agrees that, during the Term, Employee shall not engage in any other trade, business or occupation that will interfere with Employee's obligations to Employer, as described in this Agreement.

(b) Employee agrees that, during the Term, Employer shall have the exclusive right to Employee's performance of any media-related services and Employee shall

Employee Initials _____

not render any media-related services to any person or entity other than Employer, without the prior, written consent of Employer.

(c) Employee agrees not to perform Services, authorize or permit the use of Employee's name, image or likeness, or make personal appearances in connection with Services performed for or by any other company, business or interest, which conflicts with the full and faithful performance of Employee's duties for Employer, without the prior written consent of Employer.

(d) Employee will not prepare or provide, for publication by persons or entities other than Employer, information or materials that associate or identify Employee with Employer, and Employee will not authorize or permit the use of Employee's name or likeness in connection with the advertising of any product or service without the prior written consent of Employer.

(5) Use Of Image. Employee hereby grants Employer the royalty-free non-exclusive license to use, and the right to license others to use, Employee's name, sobriquet, voice, caricature, biography and likeness or any other rights of publicity or indicia of identity in any present or future medium worldwide. Employee acknowledges and agrees that Employee has no right of approval, no claim to any compensation, and no other claim arising out of any use described herein.

(6) Conduct.

(a) Employee acknowledges Employer's responsibility to the public and warrants that Employee always has in the past and will at all times in the future conduct him or herself with due regard to social conventions and public morals and decency, and agrees that Employee shall not commit any act or become involved in any situation or occurrence tending to degrade Employee in the mind of the public or which may bring Employee into public disrepute, contempt, scandal or ridicule, or tend to shock, insult or offend the community or which may reflect unfavorably on Employee or Employer or any sponsor of the programs hereunder or its advertising agency, whether or not information regarding such becomes public.

(b) Employee recognizes that, because of the visual nature of the television medium, Employee's personal appearance and demeanor have a great impact on the usefulness and value of the Services provided by Employee under this Agreement. Employee understands and agrees that Employer may properly consider the actual or anticipated response of its audience to Employee's personal qualities, as well as any other relevant factor, in deciding what Services Employee may be asked to provide. It is therefore agreed that Employer shall have the right to make reasonable demands from time to time regarding Employee's appearance, including, without limitation, Employee's wardrobe, hairstyle and makeup, as Employer may deem appropriate with respect to the Services Employee may be asked to provide and Employee shall comply with any such demands made by Employer.

Employee Initials ____

(7) Use of Services And Scheduling.

(a) Employee understands and agrees that this Agreement in no way restricts the right of Employer at any time, and from time to time, to change its broadcast schedule, including without limitation the time, day, length, content, format and frequency of any programs broadcast and to determine whether various programs should be originated (i) at Employer's studios or elsewhere and (ii) in live or recorded form.

(b) Employee also understands and agrees that, because of the nature of Employer's business, Employer cannot guarantee to what extent, if any, Employee will be requested to perform the Services. Accordingly, nothing in this Agreement shall be construed to require Employer to use Employee's Services or to produce, broadcast or distribute any program, or to use Employee only as talent, and Employer shall have fulfilled its obligations under this Agreement by making the payments to Employee required by this Agreement.

(c) Employer may lend and authorize the lending of Employee's Services to any program or programs produced, transmitted or otherwise distributed by Employer, its parent companies, subsidiaries or affiliates. In each such event, this Agreement will continue in full force and effect and Employer will retain its rights hereunder. Employer will pay Employee the compensation provided herein and will be entitled to keep any compensation paid to Employer for the lending of Employee's Services. Employee will render Services as Employer may agree to lend and Employer may grant to the recipient of those Services such incidental rights in connection with those Services as Employer may be entitled to hereunder. No act or omission on the part of any such recipient will constitute a breach by Employer of this Agreement, unless any such act or omission on the part of such recipient would have been a breach hereunder if done by Employer.

(8) Property Rights. Any scripts, videotapes, films, recordings, photographs and any part thereof, in which Employee has been involved with Employer in any way, shall remain the exclusive property of Employer, with Employee having no rights therein. Employee acknowledges Employer as the sole and rightful owner of any "intellectual property," including but not limited to, any programs, inventions, copyright material, trademarks, tradenames, patents, and the like, which Employee may create, prepare or procure, alone or with others, during employment with Employer, where such creation, preparation or procurement involved the use of Employer's time or resources.

(9) Confidentiality and Non-Disclosure.

(a) During the Term, Employee will have access to proprietary information and confidential records of the Station and its affiliated entities. Employee agrees that Employee will not, for so long as the information remains confidential or a trade secret under applicable law, divulge, furnish or make accessible to anyone or appropriate for Employee's own use (except as may be duly authorized to perform Employee's duties hereunder) any Confidential Information of the Station and its affiliated entities, which has been disclosed to Employee, or of which Employee became aware as a consequence of or through Employee's employment, unless required by applicable law, (including

Employee Initials ____

regulation, legal process or judicial order). For the purposes of this Agreement, "Confidential Information" is information or material that has not been made generally available to the public by the Station or its affiliated entities and is: (i) generated, collected or used in the operations of the Station or its affiliated entities and relates to the actual or anticipated business of the Station or its affiliated entities; (ii) suggested by or resulting from any task assigned to or work performed by Employee during his employment with the Station or during the Term; or (iii) received from Station entities or vendors or potential vendors or customers. Confidential Information includes, without limitation: business secrets, or business opportunities of the Station or its affiliated entities, including without limitation, marketing, political, advertising and promotional ideas and strategies, marketing surveys and analyses, technology, budgets, business plans, customer or supplier lists, research or financial, purchasing, planning data or information.

(b) Employee agrees that Employer will suffer irreparable injury if Employee uses or discloses any Confidential Information. Therefore, without limiting any other legal or equitable remedies available to it, if Employee uses or discloses or threatens to use or disclose such confidential information on behalf of Employee or others, Employer will be entitled to obtain equitable relief by injunction or otherwise from any court of competent jurisdiction, including without limitation, an injunction to prevent Employee from breaching the provisions of this Section restricting disclosure of confidential information. For purposes of this Agreement, information that is considered "trade secrets" under applicable law shall be subject to the maximum protection permitted by law.

(c) Immediately upon termination of this Agreement or at any point prior to or after that time upon the specific request of Employer, Employee shall return to Employer all written or descriptive materials of any kind in Employee's possession which contain trade secrets or confidential information and the obligations in this Agreement shall continue until their expiration under the terms of this Agreement.

(10) Restrictive Covenants. Employee agrees that, while employed by Employer and for the one-year period following termination of employment, regardless of the reason for termination:

(a) Employee shall not perform any activities that are the same as or similar to the Services (as defined above) or such other services as performed by Employee for Employer within the two-year period preceding the termination of employment or, make any personal appearances, or authorize or permit the use of his/her name, image, voice, sobriquet, biography, recorded performance, picture, portrait, caricature, electrical transcription, tape, digitized image, animated image, audio file, graphic file, text file, compact disc recording, web page or other recording or likeness for or on behalf of any Competitor without the express prior written consent of Employer (which consent may be withheld at Employer's discretion). For purposes of this Section, the term "Competitor" means any television station, radio station, cable television facility or program or any other video delivery system (including, without limitation, broadcast, cable, satellite or internet) that competes with Employer for viewers, advertisers or the like within all or any portion of the Designated Market Area ("DMA") of the Station (as currently defined by

Employee Initials ____

Nielsen Media Research) other than Employer or any entity that owns, is owned or controlled by , or licensed to, Employer.

(b) Employee shall not (directly or indirectly), on behalf of Employee or any other person or entity, hire, solicit, take away or attempt to hire, solicit or take away any person who is (or in the preceding six (6) months was) an employee, director or independent contractor of Employer or its affiliates and shall not induce or attempt to induce, or influence or attempt to influence, any person employed by Employer or its affiliates to terminate his or her employment with Employer or its affiliates.

Employee acknowledges and agrees that he/she has carefully considered the nature and extent of the restrictions upon him/her and the rights and remedies conferred upon Employer under this Agreement, and hereby acknowledges and agrees that the same are reasonable in time and territory, are designed to eliminate competition which otherwise would be unfair to Employer, do not stifle the inherent skill and experience of Employee, are fully required to protect legitimate interests of Employer, and do not confer a benefit upon Employer disproportionate to the detriment of Employee. Each of the above-recited covenants shall be deemed and shall be construed as a separate and independent covenant. Any court of competent jurisdiction which determines that the above-recited covenants or any portion thereof are overbroad or otherwise unenforceable may reform or revise such covenants to the extent necessary to conform with existing law such that the revised covenants, or portions thereof, shall be read as broadly as the law allows. Should any part or provision of any such covenants be reformed or declared invalid, such reformation or invalidity shall in no way render invalid or unenforceable any other part or provision thereof or any other separate covenant of Employee not declared invalid. Employee agrees that the injury Employer will suffer in the event of the breach by Employee of any clause of this Section 10 will cause Employer irreparable injury that cannot be adequately compensated by monetary damages alone. Therefore, Employee agrees that Employer, without limiting any other legal or equitable remedies available to it, shall be entitled to obtain equitable relief by injunction or otherwise from any court of competent jurisdiction, including, without limitation, injunctive relief to prevent Employee's failure to comply with the terms and conditions of this Section 10. The one-year period referenced in subsections (a) and (b) shall be extended on a day-for-day basis for each day during which Employee violates the provisions of subsections (a) or (b) in any respect, so that Employee is restricted from engaging in the activities prohibited by subsections (a) and (b) for the full one-year period.

(11) Termination for Cause. Employee's employment may be terminated at any time by Employer for Cause without any liability owing to Employee or Employee's beneficiaries if:

(a) Employee neglects or refuses to discharge Employee's duties or refuses to comply with any lawful instructions given to Employee;

(b) Employee commits any material breach of this Agreement; or

(c) Employee is guilty of gross misconduct.

Employee Initials

For the purposes of this Agreement the following acts shall constitute gross misconduct:

i. any act involving fraud or dishonesty;

ii. any arrest, charge or indictment for any crime constituting a felony or any misdemeanor involving moral turpitude;

iii. the carrying out of any activity that would prejudice and/or reduce the good name and standing of Employer, or would bring it into contempt, ridicule or would reasonably shock or offend the community in which Employer is located;

iv. attendance at work or at a work related function in a state of intoxication or otherwise being found in possession at Employee's place of work or at a work related function of any prohibited drug or substance, possession of which would amount to a criminal offense;

v. assault or other act of violence against any employee of Employer or other person during the course of Employee's employment; or

vi. violation of any Employer policy, including without limitation Employer's policies concerning motor vehicles, social media and political activities.

(12) Termination Upon Death or Disability. Notwithstanding anything herein to the contrary, Employee's employment under this Agreement shall end immediately upon Employee's death. In addition, Employee's employment under this Agreement shall end upon the date designated by Employer in a written notice provided to Employee following Employee's absence from work by reason of Employee's Disability. For purposes of this Agreement, the term "Disability" shall mean Employee's inability to perform the material functions of Employee's job for a period of at least sixteen weeks during any twelve-month period. In the event of a termination by reason of death or Disability, Employee shall be entitled to payment of any accrued but unpaid wages (including any accrued but unused PTO) as of the time of such termination and shall have no further right to payment (including any severance) of any kind from Employer other than payment of benefits under a retirement, health or other welfare plan in which Employee participated as of the date of Employee's termination under this Section.

(13) Other Terminations. Employer reserves the right to terminate Employee's employment under this Agreement at any time, without cause, by providing Employee four (4) weeks' written notice or paying Employee four (4) weeks' salary in lieu of four (4) weeks' notice. Following Employee's termination, Employee shall be entitled to payment of any accrued but unpaid wages (including any accrued but unused PTO) as of the time of such termination and the four (4) week payment set forth herein but shall have no further right to payment (including any severance) of any kind from Employer other than payment of benefits under a retirement, health or other welfare plan in which Employee participated as of the date of Employee's termination under this Section.

(14) Suspension. Employer may choose to suspend Employee's employment (and its obligation to pay compensation to Employee) if Employee fails or refuses to perform the services required under this Agreement properly, violates any of the terms of this Agreement, intentionally alters

Employee Initials ____

Employees physical appearance in a manner that detracts from Employees appearance (as determined by Employer) or engages in any conduct which would justify Employee's termination under the terms of this Agreement (including without limitation these Standard Terms and Conditions). Such suspension shall continue for a reasonable period of time or until Employee is able and willing to perform the services properly, provided however that any suspension shall be no less than one work week in length and, if longer than one work week shall be extended in weekly increments. Employer, at its option, may extend the Initial Term or any Option Period for the length of any such suspension(s) by giving notice of the extension to Employee. Employer's decision to suspend Employee's employment under this Section will not affect Employer's right to terminate Employee's employment before Employee becomes willing and able to resume performing the services properly or after any subsequent incident which would justify termination under this Agreement.

(15) Governing Law. This Agreement shall be governed by the laws of the State in which the principal business offices of the Station are located and the rights and obligations of the parties hereunder shall be construed and enforced in accordance with such laws without regard to principles of conflict of laws. The parties submit to the exclusive jurisdiction and venue of any local, state or federal court located within the State in which the principal business office of the Station are located for resolution of any and all claims, causes of action or disputes arising out of, related to or concerning this Agreement and the parties agree to waive any claim relating to forum non conveniens.

(16) Waiver of Jury Trial. The parties acknowledge and agree that any suit, action or proceeding, whether claim or counterclaim, of any kind or nature brought by either party arising out of the interpretation, enforcement or breach of this Agreement shall be resolved by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury of any such suit, action or proceeding.

(17) Binding Agreement. This Agreement shall be binding upon and inure to the benefit of Employee, together with Employee's heirs and personal representatives, and Employer, its successors and assigns.

(18) Waiver. The waiver by either party of a breach of any provision contained in this Agreement shall not be construed as or operate as a waiver of any subsequent breach.

(19) Severability. If any one or more of the terms, provisions, covenants or restrictions of this Agreement shall be determined by a court of competent jurisdiction to be invalid, void or unenforceable, then the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect, and to that end, the provisions hereof shall be deemed severable.

Employee Initials ____

Letter #136, 2021, Wed, Oct 27: Viganò to Gomez

Letter #136, 2021, Wed, Oct 27: Archbishop Viganò's Open Letter to Archbishop Gomez

Archbishop **Carlo Maria Viganò**, 80, has written an open letter to America's bishops expressing concern about various issues concerning the Coronavirus, and the vaccinations against the virus.

The central concern of the former Vatican nuncio to the United States (2011-2016) is that the testing of the various vaccines has not yet been completed, and will not be completed in many cases until 2023 or 2024.

Since there are already after nine months of vaccinations a number of reported cases of negative reactions to the vaccines, Viganò says that he, and other bishops, ought to be concerned about the announced plan of **US President Joseph Biden** (link) to vaccinate in the near future 28 million American children between the ages of 5 and 11.

Since these children have, statistically, faced little danger from the Coronavirus, but might face some type of negative side effect from the untested vaccines, Viganò argues that it would be more prudent to postpone such massive vaccinations plans for such young children until the testing is complete.

To persist in carrying out the plan would be a crime, Viganò maintains.

The letter contains many footnotes to scientific articles — some little noted by the mainstream media — which the archbishop believes support his arguments.

"I realize that it may be extremely unpopular to take a position against the so-called vaccines," Viganò writes to Gomez, "but as Shepherds of the flock of the Lord we have the duty to denounce the horrible crime that is being carried out."

Here is Viganò's text, when he sent to me yesterday, October 26, though the text is dated October 23, four days ago. —*RM*

To His Excellency
Msgr. José Horacio Gómez
Metropolitan Archbishop of Los Angeles
President of the United States Conference of Catholic Bishops

To Their Eminences and Excellencies
The Archbishops and Bishops of the Dioceses of the United States of America

And, for their competence:

To His Eminence
Cardinal Luis Francisco Ladaria Ferrer, s.j.
Prefect of the Congregation for the Doctrine of the Faith

To His Eminence
Cardinal Gerhard Ludwig Müller
Prefect emeritus of the Congregation for the Doctrine of the Faith

23 October 2021

Your Eminences,

Your Excellencies,

I address you, Archbishop Gómez, as President of the United States Conference of Catholic Bishops, and to You, Cardinals Ladaria and Müller, for your competence, some serious considerations related to the so-called vaccines against Covid-19.

I believe there are some aspects of the question that now allow for a more complete evaluation of what these drugs are and what effects they cause; this evaluation ought to lead to a collegial stance, in conformity with the Magisterium of the Church and not influenced by biased information or by erroneous news spread by the producers of these drugs or by the media.

1. Subject of the Note of the Congregation for the Doctrine of the Faith

The *Note on the morality of using some anti-Covid-19 vaccines* was issued last year in the absence of complete data on both the nature of the gene serum and its components. I point out to You that the subject of the Note is limited to "*the moral aspects of the use of the vaccines*

against Covid-19 that have been developed from cell lines derived from tissues obtained from two fetuses that were not spontaneously aborted,"[1] and it states that "*[w]e do not intend to judge the safety and efficacy of these vaccines, although ethically relevant and necessary, as this evaluation is the responsibility of biomedical researchers and drug agencies*."[2] Safety and effectiveness are thus not the subject of the Note, which in expressing its opinion about the "*morality of use*" therefore does not even express its opinion about the "*morality of production*" of these drugs.

2. Safety and effectiveness of the vaccines

The safety and effectiveness of individual vaccines is determined after a period of experimentation that normally lasts for several years. In this case, the health authorities have decided to carry out experimentation on the entire world population, as an exception to the usual practice of the scientific community, international standards, and the laws of individual nations. This means that the entire population finds itself in the condition of being susceptible to suffering the adverse effects of the vaccine, at their own risk, when normally experimentation is done on a voluntary basis and carried out on a limited number of subjects, who are paid to undergo it.

I think it is clear that this is an experimental drug that has not been approved,[3] but only authorized for administration by the bodies in charge; just as I think it is evident that there are medical treatments without adverse side-effects, even though they have been systematically boycotted by the Health Institutions – WHO, CDC, EMA – and by mainstream media. Even if the Church should express a moral evaluation of the different treatments available – some of which are carried out with drugs

produced with cell lines that originated in an aborted fetus, like the vaccines – it must be reiterated that there are effective treatments which cure patients and allow them to develop permanent natural immune defenses, something that the vaccines do not do. Furthermore, these treatments do not cause serious side effects, since the drugs that are used have been licensed for decades.

Other recently developed treatments are absolutely effective, inexpensive, and carry no danger for those who receive them: this is the case with the *plasma treatment* studied and employed with great success by the Italian doctor Giuseppe De Donno.[1]

Treatment with hyper-immune plasma was strongly discouraged and boycotted by pharmaceutical companies and doctors financed by them, because it does not cost anything and renders the analogous therapy useless, which is made in laboratories with monoclonal cells at exorbitant costs.

International standards specify that an experimental drug cannot be authorized for distribution except in the absence of an effective alternative treatment: this is why drug agencies in the USA and Europe have prevented the use of hydroxychloroquine, ivermectin, hyper-immune plasma, and other therapies with proven effectiveness. There is no need to remind You that all of these agencies, along with the WHO, are financed almost entirely by the pharmaceutical companies and by foundations tied to them, and that there is a very grave conflict of interest at the highest levels,[2] about which the media are culpably silent.[3] In expressing a moral evaluation of the vaccines, the Church cannot fail to take these elements into consideration, since they cause a manipulation of scientific

information, on the basis of which the judgments about their moral liceity by ecclesiastical Authority have been formulated.

3. The experimental drugs are not vaccines in the proper sense

The Congregation for the Doctrine of the Faith, while not expressing its opinion on the effectiveness and safety of the so-called vaccines, nevertheless defines them as "vaccines," taking for granted that they actually give immunity and protect people from active and passive contagion. This element is disavowed by the declarations coming from all of the world's health authorities and from the WHO, according to which vaccinated people can become infected and infect others more seriously than those who are not vaccinated[4] and find that their immune defenses are drastically reduced if not even completely destroyed.

A recent study confirms that the gene serum can cause forms of acquired immuno-deficiency in those who receive it.[5] Therefore, the drugs that are called "vaccines" do not fall within the official definition of a vaccine to which the CDF's Note presumably refers. In fact a "vaccine" is defined as a medicinal preparation aimed at inducing the production of protective antibodies by the organism, conferring specific resistance against a specific infectious disease (viral, bacterial, protozoal). This definition was recently changed by the WHO, because otherwise it would not have been able to include anti-Covid drugs, which do not induce the production of protective antibodies and do not confer a specific resistance against the SarsCoV-2 infectious disease.

Furthermore, while mRNA serums are dangerous because of the implications they have at the genetic level, the Astra Zeneca serum may be even more harmful, as recent studies show.[6]

4. Proportionality between the costs and benefits of the vaccines

Limiting itself to an evaluation only of the morality of the use of the vaccines, the Congregation for the Doctrine of the Faith does not take into account the proportionality between the presumed benefits of the gene serum and the short-term and long-term adverse side effects.

Worldwide, the number of deaths and grave pathologies following vaccination is increasing exponentially:[7] in only nine months these vaccines have caused more deaths than all vaccines in the last thirty years.[8] Not only this: in many nations – such as Israel for example[9] – the number of deaths after vaccination is now greater than the number of deaths from Covid.[10]

Having established that the drugs sold as vaccines do not give any significant benefit and on the contrary may cause a very high percentage of deaths or grave pathologies[11] even in subjects for whom Covid does not represent a threat,[12] I do not think that we can conclude that there is any proportionality between the potential damages and the potential benefits.

This means therefore that there is a grave moral obligation to refuse inoculation as a possible and proximate cause of permanent damages[13] or death. In the absence of benefits, there is therefore no need to expose

oneself to the risks of its administration, but on the contrary there is a duty to refuse it categorically.

5. New data on the presence of aborted fetal cell lines

Revelations from Pfizer executives have recently been released showing that the mRNA gene serums contain aborted fetal material not only for the production of the original vaccine, but also for its replication and production on a vast scale,[14] and nothing suggests that other pharmaceutical companies are an exception. Bishop Joseph Strickland[15] has also expressed himself in this regard, inviting the faithful to "*say no. I'm not going to do it just because you mandate it, in that, who knows what next crazy thing will come up.*" This makes the use of these drugs absolutely immoral, just as it is immoral and unacceptable to use drugs that use orphaned children for experimentation.[16]

6. Side Effects on pregnant mothers and nursing children

Another aspect to consider is the concrete danger of grave side effects on pregnant mothers and even more serious ones on newborn children: in the United States there have been 675 miscarriages in vaccinated mothers and in the United Kingdom 521 nursing infants have died.[17] We should remember that for the so-called vaccines against Covid active vigilance was not put into effect, but only passive vigilance, which requires patients to report adverse cases themselves; this means that the data on adverse effects should be multiplied at least ten times.

7. Components of the vaccines

I would like to point out to You that the components of the gene serums are still concealed as trade secrets, even if there are already multiple studies that have analyzed the content of the vaccines;[18] it is therefore not yet possible to completely evaluate the other critical elements and their long-term impacts, because the experimentation on the world population will end only in 2023/2025, and it is not known what the effects of the newly adopted technology are at the genetic level.[19] The presence of graphene in the doses that have been administered, reported by numerous laboratories that have analyzed its content,[20] suggests that the forced use of so-called vaccines – together with the systematic boycott of existing treatments of proven effectiveness[21] – serves the purpose of contact-tracing all vaccinated human beings throughout the world, who will be or already are connected to the *Internet of Things*[22] by means of a quantum link of pulsed microwave frequencies of 2.4 GHz or higher from cell towers and satellites.[23] As proof that this information is not the fruit of the fantasies of some conspiracy theorist, You should know that the European Union has chosen two projects dedicated to technological innovation as the winners of a competition: "The Human Brain" and "Graphene." These two projects will receive one billion euro each in funding over the next ten years.[24]

I trust that Your Excellency, Archbishop Gomez, will take into serious consideration these observations of mine – which I have taken care to thoroughly verify with highly qualified Catholic doctors[25] – together with your brothers of the US Bishops' Conference gathered in plenary Assembly from November 15 to 18, 2021 in Baltimore, so that the official position of the Catholic Church in the United States on the so-called vaccines will be revised and

updated. Likewise, I ask Your Eminence, Cardinal Ladaria, to proceed as soon as possible to the revision of the *Note* of the Congregation for the Doctrine of the Faith *on the morality of certain anti-Covid-19 vaccines*.

I realize that it may be extremely unpopular to take a position against the so-called vaccines, but as Shepherds of the flock of the Lord we have the duty to denounce the horrible crime that is being carried out, whose goal is to create billions of chronically ill people and to exterminate millions and millions of people, based on the infernal ideology of the "Great Reset" formulated by the President of the *World Economic Forum*Klaus Schwab and endorsed by institutions and organizations around the world.[26]

The silence of so many Cardinals and Bishops, along with the inconceivable promotion of the vaccination campaign by the Holy See, represents a form of unprecedented complicity that cannot continue any longer. It is necessary to denounce this scandal, this crime against humanity, this satanic action against God.

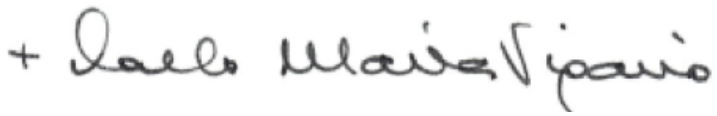
With every passing day, thousands of people are dying or are being affected in their health by the illusion that the so-called vaccines guarantee a solution to the pandemic emergency. The Catholic Church has the duty before God and all of humanity to denounce this tremendous and horrible crime with the utmost firmness, giving clear directions and taking a stand against those who, in the name of a pseudo-science subservient to the interests of the pharmaceutical companies and the globalist elite, have only intentions of death. How Joe Biden, who also defines himself as "Catholic," could impose vaccination on 28 million children aged 5 to 11,[27] is absolutely inconceivable, if only for the fact that there is practically zero risk of

them developing the SARS-CoV-2 disease. The Holy See and the Bishops' Conferences have the duty to express a firm condemnation in this regard, and also in relation to the very serious side effects that can result for children who are inoculated with the experimental gene serum.[28]

It is equally imperative that there be an intervention by the US Bishops' Conference aimed at promoting the *religious exemption* and immediately revoking the bans imposed in this regard by many Ordinaries on their priests. Similarly, all vaccination requirements for seminarians and candidates of religious communities must be revoked. Instead, clear directives should be given about the dangers connected to the administration of the vaccine and its grave moral implications.

I am certain that You will want to consider the particular gravity of this subject, the urgency of an intervention that is enlightened by and faithful to the teaching of the Gospel, as well as the *salus animarum* that the Pastors of the Church must promote and defend.

In Christo Rege,



+ Carlo Maria Viganò, *Archbishop*

Notes:

[1] Congregation for the Doctrine of the Faith, *Note on the morality of using some anti-Covid-19 vaccines*, 21 December 2020.

[2] *Ibid.*

[3] Senator Ron Johnson: *We don't have an FDA-approved vaccine in the US. The vaccine (Pfizer Comirnaty) available in Europe is approved, but the vaccine (Pfizer BNT162b2) used in America only has the use of emergency clearance.* – Cfr. https://twitter.com/ChanceGardiner/status/1445262977775534081?s=20

[4] Cf. https://pubmed.ncbi.nlm.nih.gov/32838270/ e https://alloranews.com/covid-19/giuseppe-de-donno-hyperimmune-plasma-doctor-takes-own-life/

[5] *Pfizer has now hired 22 separate lobbying firms, all in Washington, DC, to craft drug policy in the United States. Yes, that's the accurate #. TWENTY TWO lobbying firms. Tons of top Congressional staffers & fmr WH officials have been recruited to push Pfizer's agenda in DC.* – Cf. https://twitter.com/JordanSchachtel/status/1444661196792205316

[6] *Founders and researchers of pharmaceutical firms have been replaced by investment funds that seek only economic results and now finance #OMS and #EMA who decide on vaccines* – Cf. https://twitter.com/CathVoicesITA/status/1448173045248581632?s=20 | *In Italy there are 32000 doctors paid by BigPharma* – https://www.ogginotizie.eu/ogginotizie/in-rete-il-report-aifa-32000-medici-pagati-dalle-case-farmaceutiche/

[7] Cf. https://tv.gab.com/channel/white__rabbit/view/breaking-pfizer-scientists-your-covid-antibodies-615b96bcd7e86658494198of and https://www.lifesitenews.com/news/ontario-er-doctor-resigns-over-mandatory-vaccines-and-falsehoods/ > *Ontario*

doctor resigns over forced vaccines, says 80% of ER patients with mysterious issues had both shots.

[8] Cf. https://twitter.com/alexgiudetti/status/1448528719673430016 and https://theexpose.uk/2021/10/10/comparison-reports-proves-vaccinated-developing-ade/ > *A comparison of official Government reports suggest the Fully Vaccinated are developing Acquired Immunodeficiency Syndrome.*

[9] Cf. https://climatecontrarian.com/2021/05/28/revealed-why-the-oxford-astrazeneca-jab-is-even-more-dangerous-than-the-mrna-vaccines/

[10] *Autopsies performed in Germany on deaths after the vaccine, the study of pathologists, 50% of deaths after the second dose were caused by the vaccine.* – Cf. https://corrierequotidiano.it/cronaca/morti-da-vaccino-patologi-il-50-dopo-la-seconda-dose/

[11] *In just 9 months, death reports from Covid-19 preparations have reached 50% of ALL post-vaccine deaths administered in 30 years in the US* – Cfr. https://infovax.substack.com/p/in-soli-9-mesi-le-segnalazioni-di– See also https://wonder.cdc.gov/controller/saved/D8/D188F890

[12]Cf. https://visionetv.it/israele-terza-dose-il-ministero-rassicura-ma-i-cittadini-indignati-replicano-in-massa/ and https://www.gov.il/he/Departments/publications/reports/seav-25092021

[13] Cf. https://twitter.com/bisagnino/status/1448644321327022090?s=20and https://infovax.substack.com/p/morti-per-covid-19-prima-e-dopo-leand https://infovax.substack.com/p/i-tassi-di-miocarditi-post-vaccino

[14] 155,501 anaphylactic reactions reported to VAERS, with 41% of cases attributed to Pfizer – Cf.https://twitter.com/ChanceGardiner/status/1446184707964739584?s=20 and (link)

[15] *The post-vaccine myocarditis rates found in young Americans (12-15 years) are 19 TIMES higher than the normal background values for these age groups.* – Cfr. https://infovax.substack.com/p/i-tassi-di-miocarditi-post-vaccino | Also see https://www.sirillp.com/wp-content/uploads/2021/10/Letter-Regarding-Covid-19-Vaccine-Injuries-Dr-Patricia-Lee.pdf | *Investigation: Deaths among Teenage Boys have increased by 63% in the UK since they started getting the Covid-19 Vaccine according to ONS data.* – Cf. https://theexpose.uk/2021/10/04/teen-boy-deaths-increased-by-63-percent-since-they-had-covid-vaccine/

[16] *In Turkey, Dr. Fatih Erbakam, leader of the Welfare party, denounces the birth of children with tails, 3 arms, 4 legs, after the vaccination of parents, against Covid.* – Cf. https://www.lapekoranera.it/2021/10/08/turchia-vaccino-dott-fatih-erbakam-i-bambini-nascono-con-la-coda-con-3-braccia-e-4-gambe-video/

[17] *The COVID-19 vaccine was developed using a fetal cell line. So were Tylenol, ibuprofen...and ivermectin.* – Cf. https://vajenda.substack.com/p/the-covid-19-vaccine-was-developed | *Pfizer Whistleblower Releases Emails Hiding 'Fetal Cell' Usage From Public* – Cf. https://thecharliekirkshow.com/columnists/charlie-kirk/posts/pfizer-whistleblower-releases-emails-hiding-fetal-cell-usage-from-public | *Pfizer Told Scientists To Coverup Use Of Aborted Human Fetal Tissues In Making Vaccines Says Whistleblower* – Cf. https://greatgameindia.com/coverup-aborted-fetal-tissues-vaccines/ and

https://twitter.com/ChanceGardiner/status/1446120608970932231 | *Process-related impurities in the ChAdOx1 nCov-19 vaccine.* – Cf. https://www.researchsquare.com/article/rs-477964/v1

[18] *US bishop slams Pfizer after emails show company wanted to hide jab's connection to abortion* – Cf. https://www.lifesitenews.com/news/us-bishop-slams-pfizer-after-emails-show-company-wanted-to-hide-jabs-connection-to-abortion/

[19] *Pfizer stand accused of experimenting on orphan babies to test their Covid-19 vaccine.* – Cf. https://theexpose.uk/2021/10/01/breaking-pfizer-stand-accused-of-experimenting-on-orphan-babies-to-test-their-covid-19-vaccine/

[20] *«CDC issues an urgent warning strongly recommending the vaccination of pregnant women», despite not having enough studies, 675 abortions in vaccinated mothers in the USA, 521 in the UK, babies who died during breastfeeding from vaccinated mothers, and Pfizer who will carry out the study only in the 2025*

Cf. https://twitter.com/ChanceGardiner/status/1443701760833511426?s=20

[21] *CoV-19 Vaccine Ingredients Revealed: Scanning and transmission electron microscopy reveals PEG, graphene oxide, stainless steel and even a parasite.*

Cf. https://www.databaseitalia.it/rivelati-ingredienti-dei-vaccini-cov-19-microscopia-elettronica-a-scansione-e-trasmissione-rivela-ossido-di-grafene-acciaio-inossidabile-e-anche-un-parassita/

[22] See the interview to Jean-Bernard Fourtillan, professor and expert in pharmacology and toxicology:https://twitter.com/Side73Dark/status/1448316251663736840?s=20

[23] Dr. Mariano Amici, Graphene and PEG oxide in vaccines: https://www.marianoamici.com/ossido-di-grafene-e-peg-nei-vaccini/

[24] Prof. Peter McCullough, pioneer of early care, has a cracked voice evoking the abandonment to death of elderly patients.Cf.https://twitter.com/ChanceGardiner/status/1446240498029670405?s=20

[25] World Economic Forum, These are the top 10 tech trends that will shape the coming decade, according to McKinsey Cf.https://www.weforum.org/agenda/2021/10/technology-trends-2021-mckinsey

[26] Exclusive: Pfizer patent approved for monitoring vaccines around the world – Cf. https://www.databaseitalia.it/esclusivo-brevetto-pfizer-approvato-per-il-monitoraggio-dei-vaccinati-in-tutto-il-mondo-tramite-microonde-e-grafene

[27] EU: The greatest research excellence award for the "Graphene" and "Human Brain" projects – Cfr.https://www.isprambiente.gov.it/it/archivio/notizie-e-novita-normative/notizie-ispra/2013/01/ue-il-piu-grande-premio-di-eccellenza-nella-ricerca-ai-progetti-grafene-e-cervello-umano | Graphene and Human Brain Project win largest research excellence award in history, as battle for sustained science funding continues. – Cfr.https://ec.europa.eu/commission/presscorner/detail/en/IP_13_54

[28] *Government, Dr. Citro: «Either they are ignorant or higher orders wanted the dead» – Cfr. https://stopcensura.online/dott-citro-contro-governo-o-sono-ignoranti-oppure-ordini-superiori-volevano-i-morti/*

[29]Listen what Bill Gates said: https://twitter.com/ZombieBuster5/status/1444245496701272065

[30] *White House Details Plan To "Quickly" Vaccinate 28 Million Children Age 5-11* – Cf. https://www.zerohedge.com/covid-19/white-house-details-plan-quickly-vaccinate-28m-children-age-5-11

[31] Robert W Malone: «*This is just sick. And heartbreaking, both literally and figuratively. This must stop*» Cf.https://twitter.com/rwmalonemd/status/1450869124947578880?s=21

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S Ma Erlinda Cruz

I praise God for you, your Eminence Cardinal Carlo Maria Vigano
for this letter of yours.
I have been praying for the leaders of the Church to stand up, and speak up on this crime against humanity that requires all to receive the covid 19 vaccines. I thank Jesus for your concern and love for the People of God. I feel empowered, enlightened and liberated by every word you have written here.
Thank you very much.
Praying for your intentions and the intentions of all Catholic doctors and medical experts who are with you in this advocacy.
In all things, may God's most holy will be done.

Like · Reply · 3 · 3w

Kristoffer Lance

Absolute insanity. Vaccines are hooking up the world's population to the internet is a topic that should be handled by Infowars, but I am sure they woud believe it to be too crazy.

Like · Reply · 3w

Leo Casey

But we already knew that you represented the neo-fascist wing of the Catholic hierarchy, working to undermine the Pope at every turn. You didn't need to confirm it for us.

Like · Reply · 2w

Mike Killion

You are the fascist Leo

Like · Reply · 2w

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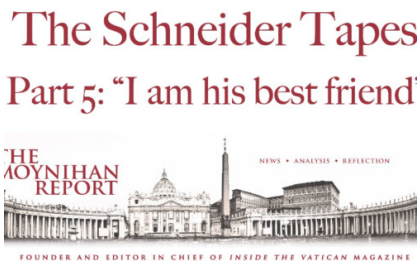

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Religious Accommodation Request Form

Instructions

Gray complies with Title VII of the Civil Rights Act of 1964, and all applicable state and local employment practices laws, and provides equal employment opportunities to all individuals, regardless of their religious beliefs and practices or lack thereof. Consistent with this commitment, the Company will provide a reasonable accommodation of an applicant's or employees sincerely held religious belief if the accommodation will resolve a conflict between the individual's religious beliefs or practices and a work requirement, unless doing so would create an undue hardship for the Company. As set forth in the Company's Religious Accommodation policy, Employees who believe they need an accommodation because of their religious beliefs or practices, or lack thereof are responsible for requesting a reasonable accommodation from their direct supervisor, General Manager or Corporate HR. Requests for accommodation may be verbal or in writing; however, Gray encourages employees to make requests in writing using this form.

As soon as possible after your need for an accommodation is known, please submit a completed copy of this form to Corporate HR at sharel.bend@gray.tv. If you need extra space to complete this form, please attach additional pages.

Upon receipt of your completed form, Corporate HR will contact you as soon as practicable to discuss your accommodation request, clarify your needs, and, if necessary, request and/or gather additional information from you. It is important that the Company and you engage in this interactive process. Please respond promptly to any communications you receive from Corporate HR relating to your request.

If you have any questions about the accommodation process, the status of your request specifically or completion of this form, please contact Corporate HR.

Employee Information

Name: **David S. Platta** Department: **News (Sports Director)**

Date of request: **9 September 2021**

Immediate supervisor: **DeLoris Washington (Ass't ND) / Holly Steuart (GM)**

Requested accommodation (job change, schedule change, dress/appearance code exception, vaccination exemption, etc.):

Vaccination exemption

Length of time the accommodation is needed: **Indefinite**

Describe the religious belief or practice that necessitates this request for accommodation:

See attachment

Describe any alternate accommodations that might address your needs:

See attachment

I have read and understand Gray Television's policy on religious accommodation. My religious beliefs and practices, which result in this request for a religious accommodation, are sincerely held. I understand that the accommodation requested above may not be granted but that the company will attempt to provide a reasonable accommodation that does not create an undue hardship on the company. I understand that Gray may need to obtain supporting documentation regarding my religious practice and beliefs to further evaluate my request for a religious accommodation.

Addendum to Exemption request:

Catholic teachings over the centuries have dealt with bodily integrity in great detail, including vaccines. The Congregation for the Doctrine of the Faith published guidelines on COVID vaccines [1] in December of 2020, restating that vaccines with connections to aborted fetuses are morally compromised.

The Pfizer vaccine was tested using what has been designated the "HEK-293 cell line" which originated from a child aborted in the Netherlands in 1972.[2] There is a moral duty to avoid such vaccines.

The paper went on to state that the moral duty is not obligatory if there is a grave danger of uncontainable spread, and that if the vaccines were recognized as safe and effective they could be used in good conscience. But it was also stated that "vaccination is not, as a rule, a moral obligation, and that, therefore, it must be voluntary."

Therein lies the rub. All of the elements listed must be satisfied, or else the duty to avoid the vaccines is an obligation. To do otherwise is a violation of my faith. As a Catholic, it means it is incumbent upon me to evaluate evidence myself and make my own decision on the matter because, to repeat, "It must be voluntary."

The mandating of the vaccination is the problem here. I believe that this is a big mistake, no matter how well intentioned. And let me add that I do believe the motives here are indeed well intentioned. Gray's treatment of employees during the pandemic up to this point is something that should have been emulated by other companies.

But this decision opens up a lot of unintended issues; including legal ones that leave the company wide open to what could be expensive consequences. That would be a discussion for another time.

From a moral standpoint, Gray would be better served by emphasizing prudent actions in an attempt to slow/halt the pandemic. You see, the paper also stated that those who refuse on moral grounds have a duty to avoid "by other prophylactic means and appropriate behavior, becoming vehicles for transmission of the infectious agent."

With that decision, it becomes my duty to follow through with proper behaviors to not become a "transmission vehicle" for the virus.

There are two other forms of protection that equal or better the vaccines available – natural immunity from recovery from a prior COVID infection, and from a prophylactic regimen involving currently available drugs used in combination with supplements.

I have been prescribed hydroxychloroquine (200mg) to be taken weekly. In addition, I am taking on a daily basis zinc (50mg), Vitamin D (5000 IU), Vitamin C (700mg), and quercetin (250mg) as supplements in support. Information on current studies on the efficacy of hydroxychloroquine can be found at https://hcqmeta.com/#conclusion with other links on that site if you wish to dive deeper into the data.

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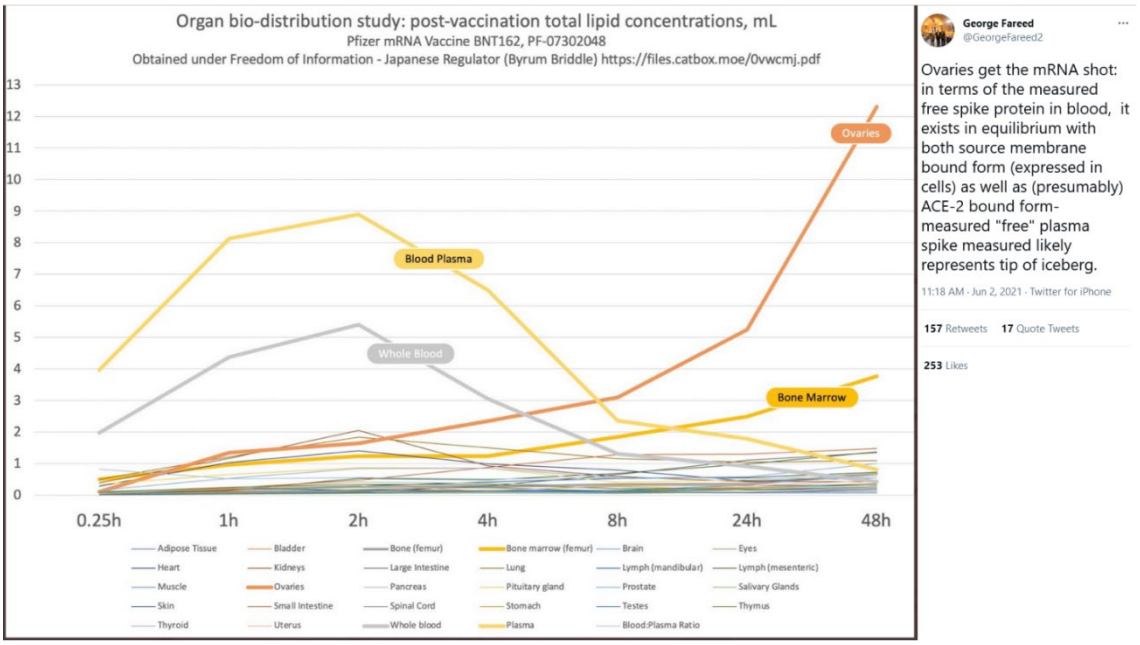
[1] https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html

[2] https://www.usccb.org/moral-considerations-covid-vaccines

I would be more than happy to sign something weekly verifying that I'm following this protocol.

There are other concerns about the safety of the COVID vaccines. Apparently the S-Protein in the shot is not acting as expected, and instead of winding up in the liver to be eliminated after activating the immune system,[3] it is traveling elsewhere in the body (specifically bone marrow and ovaries) and causing damage, including myocarditis and pericarditis in young men, as per the CDC.[4]



There is also evidence[5,6] that the S-Protein by itself is enough to cause damage, with symptoms similar to COVID-19 infection, which seems to be totally unexpected by the vaccine developers.[7] And we have no idea what the long-term effects will be since we only have approximately one year's worth of data.

That is bad enough. What is worse from a moral standpoint is the evidence that the S-Protein is affecting the ovaries and reproductive systems of women of childbearing age, and that without question is a serious problem in the Catholic faith, where the creation of life is sacred. The possibility of infertility is an unacceptably high risk – and I say that as someone who is awaiting the birth of his second grandchild in the next five months. Forcing young people to take this risk by mandating vaccination when safer alternatives are available and known is unethical, inhumane, and in violation of my Catholic faith.

Preferably, the vaccine mandate would be eliminated and the safer alternative of antivirals and supplements would be promoted, but failing that, female employees should be exempted.

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[3] https://blogs.sciencemag.org/pipeline/archives/2021/05/04/spike-protein-behavior
[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
[5] https://www.ahajournals.org/doi/full/10.1161/CIRCRESAHA.121.318902
[6] https://www.contagionlive.com/view/spike-protein-of-sars-cov-2-virus-alone-can-cause-damage-to-lungs
[7] https://podcasts.apple.com/us/podcast/how-to-save-the-world-in-three-easy-steps/id1471581521?i=1000525032595

From: GrayTV - HR Communications <hr.comm@gray.tv>
Date: September 11, 2021 at 1:40:29 PM EDT
To: GrayTV - HR Communications <hr.comm@gray.tv>
Subject: URGENT: Update Regarding Your Vaccination Status

Dear Gray Supervisor,
The health and safety of our employees is a top priority. As you know, to help make our work environment safer, Gray Television adopted a vaccine policy in August that

requires, among other things, that all Supervisors to be FULLY VACCINATED against COVID-19 (as defined by the CDC) no later than September 15, 2021.

We have reviewed your request for a reasonable accommodation from this condition of employment. Your job position, however, requires close contact with other individuals to fulfill the essential duties of your job. This means that no reasonable accommodation is available for your current role. Therefore, if you are not fully vaccinated against COIVD-19 by September 15, 2021, you will not be qualified to remain employed with Gray Television on that date.

Nevertheless, if you are not fully vaccinated but now decide to start or complete the vaccination regime, you may request a short extension of the fully vaccinated deadline to come into compliance with the policy. To request this extension, you will need to receive, and provide proof of, the first vaccine shot and submit a timely request for this extension to vaccine@gray.tv prior to September 15, 2021. For vaccines that requires two doses, you will need to receive the second dose within the period specified for the vaccine you receive and provide us with proof of a timely second vaccination shot to extend the deadline through the end of the vaccination regime. An employee who is not fully vaccinated during a temporary deadline extension must continue to comply with all public health precautions against the coronavirus (face-covering, social distancing, temperature checks, and the like) while within any Gray workspace or within proximity of a Gray employee, customer, contractor, or other individual for work purposes. In addition, each employee who is not fully vaccinated will need to submit a negative COVID 19 PCR test to vaccine@gray.tv at least once each week. Violations of any of these public health precautions will lead to disciplinary action up to and including termination.

If you have any questions about this notice, please email our vaccination team at vaccine@gray.tv.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

JOHN DOE #1-#14 and JANE DOE #1-#2, **Plaintiffs,** **vs.** **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, U.S. Department of Defense** **XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,** **FRANK KENDALL, in his official capacity as Secretary of the Air Force, Department of the Air Force,** **CARLOS DEL TORO, in his official capacity as Secretary of the Navy, Department of the Navy,** **JANET WOODCOCK, in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration, and** **CHRISTINE WORMUTH, in her official capacity as Secretary of the Army, Department of the Army,** **Defendants.**	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** **TEMPORARY RESTRAINING ORDER REQUESTED**

Plaintiffs, by and through the undersigned counsel, hereby complain and allege the following:

INTRODUCTORY STATEMENT

1. Plaintiffs are a group of active-duty service members from each branch of the armed services who are being subjected to unlawful COVID-19 vaccine mandates under the threat of severe punishment, including dishonorable discharge, the loss of their constitutional rights, and potential imprisonment.[1] Plaintiffs bring this action to challenge the August 24, 2021 Department of Defense ("DOD") COVID-19 vaccine mandate[2] ("DOD Mandate"), and the August 23, 2021 Food and Drug Administration's ("FDA") August 23, 2021 approval of the Pfizer/BioNTech Comirnaty vaccine ("FDA Comirnaty Approval").[3] The FDA's approval was granted in record time for the improper purpose of enabling unconstitutional federal vaccine mandates, rather than on findings that the vaccine meets statutory

[1] Plaintiffs include members of key "special populations" that were not studied in the Comirnaty clinical trials, including: (1) individuals with acquired (or "natural") immunity from COVID-19 due to documented prior infection ("Natural Immunity Plaintiffs"); (2) female service members who are pregnant, nursing or are attempting to become pregnant, which the FDA refers to as "Woman of Childbearing Potential" ("WOCBP Plaintiffs"); and (3) other medical conditions or medical history that may put them at additional risk of side effects or adverse reactions to vaccines. Certain Plaintiffs have requested religious exemptions, which are still pending and are not addressed herein.

[2] *See* Ex. 2, Secretary of Defense Lloyd Austin, III, "Memorandum for Senior Pentagon Leadership, Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members" (Aug. 24, 2021) ("DOD Mandate").

[3] *See* Ex. 3, FDA, BL 125742/0, Comirnaty Vaccine BLA Approval (Aug. 23, 2021) ("Comirnaty Approval Letter"), available at: https://www.fda.gov/media/151710/download (last visited Oct. 4, 2021).

requirements or that the vaccine has demonstrated long-term safety, efficacy, or public health benefits. Plaintiffs seek emergency declaratory and permanent injunctive relief to enjoin implementation of the DOD Mandate and to stay and vacate the FDA Comirnaty Approval.

2. **FDA Vaccine Emergency Use Authorizations ("EUA").** On December 11, 2020, the Food and Drug Administration ("FDA") granted an EUA for the Pfizer-BioNTech COVID-19 vaccine (BNT16b2 or "BioNTech Vaccine"); followed by the December 18, 2020 EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine") and the February 27, 2021 EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine," and together with the BioNTech Vaccine and the Moderna Vaccine, the "COVID-19 EUA Vaccines").

3. **FDA Comirnaty Approval and EUA Extension.** On August 23, 2021, Defendant FDA conditionally approved the Biologics License Application ("BLA") for the Pfizer/BioNTech Comirnaty Vaccine ("Comirnaty Vaccine") for individuals 16 years or older. *See* Ex. 3, Comirnaty Approval Letter.[4] On the same day, the FDA re-issued and expanded the EUA for the BioNTech Vaccine for "booster" shots

[4] *See also* Ex. 4, FDA, *Summary Basis of Regulatory Action*, BLA 125742/0 at 27 (Aug. 23, 2021) ("FDA Comirnaty SBRA"); FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Oct. 4, 2021) ("FDA Comirnaty Press Release").

to certain individuals ("BioNTech EUA Extension").[5] According to the FDA, while the BioNTech Vaccine and the Comirnaty Vaccines are "legally distinct," the two products can be used "interchangeably." *Id.* at 2 n.8. The FDA re-issued the EUA because the licensed Comirnaty Vaccine is "not … available" in sufficient quantities for distribution. *Id.* at 5 n.9.

4. **DOD Mandate.** On the very next day, August 24, 2021, Defendant Secretary of Defense Lloyd Austin, III mandated all service members must receive "full vaccination." Ex. 2, DOD Mandate at 1. Secretary Austin enacted this mandate despite minimal hospitalization and mortality rates for military members infected with COVID-19.[6] Service members with natural immunity "are not considered fully vaccinated" or exempted, *id.* at 1, nor is there any exemption for female service members who are pregnant, nursing, or wish to become pregnant.

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[5] *See* Ex. 5, FDA, Pfizer-BioNTech EUA Letter (Aug. 23, 2021) ("BioNTech EUA Expansion Letter"), available at: https://www.fda.gov/media/150386/download (last visited Oct. 4, 2021).

[6] As of September 15, 2021, there have been a total of 238,120 cases among military personnel since the beginning of the pandemic in January 2020 (*i.e.*, approximately 20 months). Of these, 2,175 (or less than one percent) were hospitalized, with a total of 46 deaths (*i.e.*, less than 0.02 percent or less than one per 5,000 cases). *See* U.S. Department of Defense, "Coronavirus: DOD Response," Table "DOD COVID-19 Cumulative Totals," available at: https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/ (last visited September 19, 2021).

5. **Armed Services Guidance.** Each of the Armed Services has issued implementation guidance. *See* Ex. 6-9 (collectively, "Armed Services Guidance") and Section III.C. The Armed Services Guidance requires that all uniformed service members be fully vaccinated within 90 to 120 days of the issuance of the DOD Mandate (*i.e.*, November 2, 2021, for the Air Force, November 28, 2021, for the Marine Corps and Navy, and December 15, 2021, for the Army). Because "full vaccination" is defined as occurring fourteen (14) days after the final dose, most Plaintiffs must receive their first dose in the second week of October or else they will be deemed to be non-compliant and subject to disciplinary actions.

6. **Consequences for Non-Compliance.** Service members who decline vaccination may face the full range of administrative and disciplinary sanctions under the Uniform Code of Military Justice ("UCMJ") including separation, dishonorable discharge, and imprisonment. If dishonorably discharged, Plaintiffs will also lose the retirement, veterans and other government benefits they have earned through long service to their country, as well as future employment opportunities, civilian civil rights and fundamental constitutional rights, in particular, the Second Amendment right to bear arms. *See infra* Section III.D.

7. **DOD Mandate & Armed Services Guidance Claims.** Contrary to DOD regulations,[7] the DOD Mandate and the Armed Services Guidance do not provide a medical exemption for service members like Plaintiffs who have natural immunity from a previous COVID-19 infection or for female service members who are pregnant, nursing, or who want to become pregnant. The DOD Mandate is not only arbitrary and capricious, and unsupported by substantial evidence, but it violates the Administrative Procedures Act because it modified or partially repealed AR 40-562 without the required notice-and-comment rulemaking. Further, the Armed Services Guidance violates the express terms of the DOD Mandate (which permits only licensed vaccines to be mandated) because it permits the EUA BioNTech Vaccine to be administered pursuant to the mandate "as if" it were the licensed Comirnaty Vaccine (which is currently unavailable),[8] as well as the statutes and federal regulations requiring informed consent for experimental treatments. *See* 10 U.S.C. §§ 1107 and 1107a; 21 U.S.C. § 360bbb-3.

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[7] *See* Army Regulation 40-562, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (7 Oct. 2013) ("AR 40-562"). AR 40-562 applies with equal force to the Active Army, the Army National Guard, the U.S. Army Reserves, as well as the "uniformed Departments of the Navy, Air Force, and Coast Guard (including the active and reserve components of each Service)," as well as selected DOD employees and contractors. *See* AR 40-562, ch. 3 (7 Oct. 2013).

[8] There are reports that there will not be enough doses until 2024. *See Not Enough Covid Vaccine For All Until 2024, Says Biggest Producer,* FINANCIAL TIMES (Sept. 14, 2021), available at: https://www.ft.com/content/a832d5d7-4a7f-42cc-850d-8757f19c3b6b (last visited Oct. 4, 2021).

8. **FDA Comirnaty Approval Claims.** The DOD Mandate relies on the FDA's rushed and fatally flawed Comirnaty approval that is riddled with substantive and procedural deficiencies. It typically takes 10 years or more from discovery of a vaccine to FDA approval,[9] yet the FDA approved Comirnaty in a matter of months on an "unprecedented timeline."[10] It could issue this "approval" only by ignoring or waiving substantive and procedural requirements including: (a) completion of the crucial Phase 3 clinical trial; (b) the use of "well controlled" clinical trials; (c) including in clinical trials "special populations" like those with natural immunity or pregnant or nursing women; (d) review by the Vaccine and Related Biologics Products ("VRBPAC" or "Advisory Committee"); (e) public notice and comment procedures; (f) procedural requirements in FDA regulations and industry guidance; and (g) or any process to ensure it engages in reasoned decision-making supported by substantial evidence and free from improper political interference. The FDA also ignored or dismissed studies demonstrating the superiority of natural immunity to vaccine-induced immunity and evidence of severe adverse reactions.

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[9] *See, e.g.,* Gail A. Van Norman, MD, Drugs, Devices and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC: BASIC TO TRANSLATIONAL SCIENCE, Apr. 2016;1(3):170-79.

[10] Justine Coleman, *FDA Grants Full Approval to Pfizer's COVID-19 Vaccine*, The Hill (Aug. 23, 2021) (quoting Defendant FDA Commissioner Woodcock), available at: https://thehill.com/policy/healthcare/568980-fda-grants-full-approval-to-pfizers-covid-19-vaccine (last visited Sept. 22, 2021).

9. **FDA & DOD "Bait and Switch."** The FDA has violated the Food, Drug & Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and service members' informed consent rights, insofar as it has determined that the Pfizer/BioNTech vaccine may be simultaneously subject to two mutually exclusive and distinct regulatory regimes (*i.e.*, both an EUA vaccine and a licensed vaccine for the same indication); that the EUA BioNTech and the licensed Comirnaty Vaccine can be used "interchangeably;" and that these products may be substituted for each other for the same indication. The Armed Services Guidance is similarly unlawful insofar as it directs providers to treat EUA-labeled or manufactured vaccines "as if" they were the licensed vaccine and to administer EUA products pursuant to the mandate. These intentional misrepresentations of the law by the FDA and the Armed Services are part of an effort to circumvent informed consent requirements, to enable mandates for unlicensed and dangerous products, and to deceive and coerce service members into taking an unlicensed and experimental vaccine that they have every right to refuse. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Doe No. 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003) ("*Rumsfeld I*").

10. **Constitutional Claims.** Notwithstanding the FDA's rubber stamping of the application, the Comirnaty Vaccine remains an essentially experimental vaccine, whose long-term safety and efficacy "is not proven." *Klaassen v. Trustees*

of Ind. Univ., --- F.Supp.3d. ---, 2021 WL 3073926, at *12 (N.D. Ind. July 18, 2021) ("*Klaassen*"). The FDA admits: "Data is not yet available to inform about the duration of protection that the [Pfizer] vaccine will provide."[11] The DOD Mandate therefore violates Plaintiffs' substantive due process right to refuse unwanted, unnecessary, and unproven experimental medical treatments. The DOD Mandate violates Due Process and imposes unconstitutional conditions by forcing Plaintiffs to choose between violation of their constitutional rights or facing life-altering punishments. Further, the DOD Mandate violates the Equal Protection Clause insofar as this mandate, and others recently imposed through federal administrative actions, impose a sweeping and unconstitutional vaccine mandate, while exempting all aliens illegally entering the country that Plaintiffs are sworn to defend. The DOD Mandate also violates equal protection by singling them out based on their medical history or conditions. While service members have long been referred to as "GIs" (or "Government Issue"), they are not the *property* of the Armed Services, and the Constitution does not allow them to be treated as such.

11. **Separation of Powers & Federalism Claims.** In addition to violations of Plaintiffs' individual constitutional rights, the DOD Mandate and FDA Comirnaty

[11] FDA, *Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions* (Sept. 24, 2021), available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions (last visited Sept. 29, 2021).

Approval implicate larger concerns including Separation of Powers, Federalism, and the "major questions" doctrine. These unconstitutional edicts by DOD and the FDA must be struck down for the same reasons the Supreme Court twice struck down similar overreach by the Centers for Disease Control and Prevention ("CDC") in recent months.[12]

12. **Relief Requested.** Plaintiffs file this action seeking a Temporary Restraining Order, a Permanent Injunction, Administrative Stay and Declaratory Relief requesting that this Court:

(1) Declare the DOD Mandate unlawful, unconstitutional, and in violation of AR 40-562 and federal laws and regulations governing informed consent;

(2) Enjoin any implementation of the DOD Mandate by the Defendant Armed Services or other DOD components, or stay the effective date for any implementation orders pending resolution by this Court;

(3) Declare unlawful and vacate and remand the FDA Comirnaty Approval to the FDA;

(4) Declare unlawful the FDA's orders permitting the BioNTech/Pfizer vaccine to be both an EUA and licensed product simultaneously for the same indication;

(5) Declare unlawful the FDA's findings that the licensed Comirnaty Vaccine and the EUA BioNTech Vaccine can be used

[12] *See Ala. Assoc. of Realtors v. U.S. Dep't Health and Human Servs.*, --- F.Supp.3d ---, 2021 WL 1779282, *8 (D.D.C. May 5, 2021) ("*Alabama Realtors I*"), *aff'd*, 2021 WL 2221646 (D.C. Cir. June 2, 2021), *aff'd*, 2021 WL 3783142 (U.S. Aug. 26, 2021) ("*Alabama Realtors II*").

"interchangeably" or that they may be "substituted" for each other; and

(6) Declare unlawful and enjoin the administration of any EUA-labeled or manufactured vaccine pursuant to the DOD Mandate.

13. Plaintiffs seek this relief pursuant to the Administrative Procedures Act, 5 U.S.C. §§ 702 and 705, the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 and § 2202, the All Writs Act, 28 U.S.C. § 1651, and 42 U.S.C. § 1983.

PARTIES

14. Plaintiffs are active-duty or reserve duty Service members who are subject to the DOD Mandate, as implemented through the Armed Services Guidance of the branch in which they serve. Plaintiffs' declarations[13] provide additional information regarding their religious and medical exemption requests, the guidance that they have received (including orders to receive EUA vaccines in place of licensed vaccines), and threatened administrative and disciplinary actions.

15. Plaintiff Jane Doe #1 is an Officer in the Air Force stationed at Eglin Air Force Base, Okaloosa County, Florida. Jane Doe #1 is a WOCBP and would likely be injured by, and is unwilling to take, the vaccine due to a medical disorder. *See* Ex. 18, Decl. Jane Doe #1.

[13] Plaintiffs submit their declarations anonymously as Jane Doe #1 and #2 and John Doe #1 through #14. Plaintiffs will file an *ex parte* motion seeking leave of Court to file anonymously.

16. Plaintiff Jane Doe #2 is an Officer in the Marine Corps stationed at Camp LeJeune, North Carolina. She has submitted a religious exemption request that includes her lab results showing she has SARS-CoV-2 antibodies, has been denied a mission she had orders for, and has suffered adverse employment actions for vaccine refusal. *See id*. Decl. Jane Doe #2.

17. Plaintiff John Doe #1 serves in the Marine Corps. He is stationed at Camp Pendleton, California, and domiciled in Volusia County, Florida. He submitted a religious exemption request that was denied in September 2021. He faces adverse employment and disciplinary action for vaccine refusal, including removal from his current position and potentially a trial for Courts Martial. *See id.*, Decl. John Doe #1.

18. Plaintiff John Doe #2 is a senior Non-commissioned Officer ("NCO") in the Air Force stationed at Eielson Air Force Base, Alaska. He has been the subject of disciplinary action for requesting that he be administered the licensed Comirnaty Vaccine instead of the EUA BioNtech-Pfizer vaccine. *See id.*, Decl. John Doe #2.

19. Plaintiff John Doe #3 serves in the Air Force and is stationed at Hurlburt Field, Florida. He submitted a medical exemption request (due to his prior history with cancer) that was promptly denied. *See id.*, Decl. John Doe #3.

20. Plaintiff John Doe #4 is an NCO in the Air Force domiciled in Fort Walton Beach, Florida. He was ordered to get the EUA vaccine because the licensed

Comirnaty Vaccine was not available. He objected based on his previous COVID-19 infection, but was pressured into being injected with the EUA Janssen vaccine. *See id.*, Decl. John Doe #4.

21. Plaintiff John Doe #5 is an Officer in the Air Force Reserve domiciled in Delaware. He considered requesting a religious exemption, but the squadron and chaplain have repeatedly told him that religious exemptions would not be granted except for those with previously issued exemptions. He must be vaccinated by the second week of October. *See id.*, Decl. John Doe #5.

22. Plaintiff John Doe #6 is a Chief Warrant Officer in the Marine Corps. He is stationed in Twentynine Palms, California, and is domiciled in Flagler County, Florida. He has been threatened with disciplinary action and separation from service if he is not vaccinated by October 8, 2021. He requested a religious exemption but was told the command is only entertaining medical exemptions at this time. *See id.*, Decl. John Doe #6.

23. Plaintiff John Doe #7 is an NCO is the Army Reserve. He is currently stationed at Fort Leonard Wood, Missouri, and is domiciled in Santa Rosa County, Florida. He has been threatened with administrative action from non-promotional status to separation from the Army if he does not take the vaccine. His medical records indicate previous COVID-19 infection. *See id.*, Decl. John Doe #7.

24. Plaintiff John Doe #8 serves in the Navy and is stationed in Washington, DC. Despite having a religious exemption request on file since December of 2013, has been told that exemption is null & void. He is currently subject to an order to stay at home and has been threatened with dishonorable discharge for vaccine refusal. *See id.*, Decl. John Doe #8.

25. Plaintiff John Doe #9 is an Officer in the Air Force who is stationed at Eglin Air Force Base, Florida. He has a documented prior COVID-19 infection. He has been informed that medical exemptions for prior infections are not being considered. *See id.*, Decl. John Doe #9.

26. Plaintiff John Doe #10 is an Officer in the Air Force who is stationed at Fort Walton Beach, Florida. He has a prior documented COVID-19 infection. His application for a medical exemption was denied. *See id.*, Decl. John Doe #10.

27. Plaintiff John Doe #11 is an Officer in the United States Marine Corps who has a documented prior COVID-19 infection. He was told that he could not begin a religious exemption request before any mandate. He is facing imminent risk for refusing the vaccination because his refusal is viewed as non-compliance with a lawful order, which means Separation with the Administrative Separation Board and penal repercussions under the UCMJ. *See id.*, Decl. John Doe #11.

28. Plaintiff John Doe #12 serves in the United States Marine Corps and is stationed at Camp Lejeune in North Carolina. He has a documented prior COVID-

19 infection and has not received the vaccine. As a result, he was withdrawn from an assignment for which he had trained, received orders, and been processed. *See id.*, Decl. John Doe #12.

29. Plaintiff John Doe #13 is a Navy Officer stationed in Washington, D.C. He is facing a page 13 sanction and has been informed he must receive the first shot by the second week of October 2021. *See id.*, Decl. John Doe #3.

30. Plaintiff John Doe #14 is a Navy Officer stationed in Arlington, Virginia. He must receive the COVID-19 vaccine by October 24, 2021, or he will face administrative action, including non-promotional status to separation from the Navy. He also has submitted a religious exemption request that is still pending. *See id.*, Decl. John Doe #14.

31. Defendant DOD is a Department of the United States Government. It is led by the Secretary of Defense, Lloyd J. Austin, III, who issued the DOD Vaccine Mandate.

32. Defendant Department of the Air Force is a Department of the United States Government. It is led by the Secretary of the Air Force Frank Kendall.

33. Defendant Department of the Army is a Department of the United States Government. It is led by the Secretary of the Army Christine Wormuth.

34. Defendants Marine Corps and Navy are under the Department of the Navy, which is a Department of the United States Government. It is led by Navy Secretary Carlos Del Toro.

35. Defendant HHS is a Department of the United States Government. It is led by Secretary Xavier Becerra.

36. Defendant FDA is an agency of the United States Government. It is led by Acting Commissioner Janet Woodcock. Defendant FDA issued the EUA for the EUA COVID Vaccines, the FDA Comirnaty Approval, and the BioNTech EUA Extension.

JURISDICTION AND VENUE

37. This case arises under federal law, namely the Fifth, Ninth, and Fourteenth Amendments of the United States Constitution, U.S. CONST. AMENDS. V, IX, XIV; 42 U.S.C § 1983; the FDCA, 21 U.S.C. § 301 et seq.; the PHSA, 42 U.S.C. § 262 et seq.; 10 U.S.C. §§ 1107 and 1107a; the Administrative Procedures Act, 5 U.S.C. § 551, et. seq.; and AR 40-562.

38. The DOD Mandate, the FDA Comirnaty Approval, the BioNTech EUA Expansion, and the FDA Citizen Petition denial are final agency actions for which there is no other adequate remedy in a court. 5 U.S.C. § 704. These actions mark the consummation of the agency's decision-making process with respect to the DOD's imposition of a vaccine mandate, and the FDA's approval of the Comirnaty

Vaccine. Each has direct and appreciable legal and life-altering consequences for Plaintiffs and millions of other U.S. citizens.

39. Jurisdiction is proper in this Court under the Administrative Procedures Act, 5 U.S.C. § 702, and under 28 U.S.C. § 2201, which states that actions involving controversies with federal agencies may be pursued in any United States District Court, and under 28 U.S.C. §§ 1331 and 1346.

40. Venue is proper in this Court pursuant to 28 U.S.C. §1402 and 28 U.S.C. § 1391(e) because a plurality of the Plaintiffs are stationed at and/or domiciled in this district, and because a substantial part of the act or omissions giving rise to the claim, namely, the actual and imminent injury due to the unlawful and unconstitutional administration of an unwanted, unnecessary, dangerous, and unproven vaccine will occur in this district, unless this Court grants the relief requested herein.

STATEMENT OF FACTS

I. COVID-19 BACKGROUND

A. COVID-19 Discovery and Public Health Emergency

41. On January 29, 2020, the White House Coronavirus Task Force was established to oversee and coordinate the Trump Administration's response to COVID-19. On January 31, 2020, as a result of confirmed cases of COVID-19, HHS

Secretary Azar determined that a public health emergency existed as of January 27, 2020, pursuant to §319 of the PHSA, 42 U.S.C. § 247d et seq.

B. COVID-19 Mortality Risks

42. The mortality risk for those infected with SARS-CoV-2 is not the same for all age groups. Older patients are at higher risk of death if infected, while younger and healthier patients face a vanishingly small risk. The CDC's best estimate of the infection fatality rate for people ages 18-49 years is under 0.06% (34,171 deaths out of 60,461,355 cases), meaning that young adults have a 99.94% survivability rate.[14]

C. COVID-19 Risks for DOD Military Personnel

43. As of September 15, 2021, there have been a total of 238,120 documented COVID-19 cases among military personnel since the beginning of the pandemic in January 2020 (*i.e.*, approximately 20 months). Of these, 2,175 (or less than one percent) were hospitalized, with a total of 46 deaths (*i.e.*, less than 0.02 percent or less than one per 5,000 cases).[15] It is important to note that this low rate

[14] *See* CDC *Estimated COVID-19 Burden*, Table 1: Preliminary Estimated COVID-19 Cumulative Incidence, by Age Group – United States, February 2020-May 2021, available at: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html (last visited Sept. 7, 2021). The CDC's best estimate of the infection fatality rate for people aged 50-64 years is under 0.6% (116,284 deaths our of 20,375,641 cases), meaning this age group have a 99.4% survivability rate.

[15] *See* U.S. Department of Defense, "Coronavirus: DOD Response," Table "DOD COVID-19 Cumulative Totals," available at: https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/ (last visited September 19, 2021). These low mortality and hospitalization rates were

of hospitalizations and deaths were achieved with essentially no COVID-19 treatment of these service members, which could have dramatically reduced deaths.[16]

II. FEDERAL VACCINE MANDATES

44. Executive orders have been issued requiring vaccination for all federal employees[17] and federal contractors.[18] Existing requirements have been expanded to cover 17 million healthcare workers,[19] *id.*, and the Occupational Health & Safety Administration ("OSHA") has been directed to take the extraordinary step of issuing a new emergency temporary standard ("ETS") "to require all employers with 100 or more employees . . . to ensure their workforces are fully vaccinated or show a negative test at least once a week" ("OSHA Mandate") that would cover 80 million

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achieved largely without any COVID-19 treatments, which can dramatically reduce hospitalizations and mortality. *See supra* Section VI.E.

[16] *See generally* Ex. 16, *The FDA COVID-19 Drug Approval Process* at 11-12 and studies cited therein.

[17] *See* Exec. Order 14,043, 86 Fed. Reg. 50,989, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" (Sept. 9, 2021) ("Federal Employee Mandate"). This mandate appears to exempt White House personnel, CDC personnel, Congress, the U.S. Postal Service, and the federal judiciary.

[18] *See* Exec. Order 14,402, 86 Fed. Reg. 50,985, "Ensuring Adequate COVID Safety Protocols for Federal Contractors" (Sept. 9, 2021) ("Federal Contractor Mandate").

[19] *See* OSHA, Interim Final Rule, *Occupational Exposure to COVID-19; Emergency Temporary Standard*, 86 Fed. Reg. 32,376 (June 21, 2021).

workers. The Executive Branch also strongly opposes granting exemptions from vaccine mandates or any limits on imposition of the harshest possible penalties.[20]

45. Any State governors or other elected officials opposed to these plans will be moved "out of the way."[21] Many states are undeterred and have announced their readiness to challenge these federal vaccine mandates, with two dozen state attorneys general warning of "impending legal action" if the mandates go into effect.[22] It was also announced that the Department of Education ("DOE") will seek to extend vaccine mandates to all school children and employees, and that the DOE

[20] On September 2, 2021, the Executive Office issued a statement opposing a provision in H.R. 4350 – National Defense Authorization Act for Fiscal Year 2022 ("2022 NDAA") that would enact into law an exemption for service members with natural immunity from prior infections. *See* Executive Office, "Statement of Administrative Policy: H.R. 4350 – National Defense Authorization Act for Fiscal Year 2022" at 4 (Sept. 21, 2021) ("2022 NDAA Statement"), available at: https://www.whitehouse.gov/wp-content/uploads/2021/09/SAP-HR-4350.pdf (last visited Sept. 23, 2021).

[21] *See* Jon Brown, *Biden declares war on DeSantis and Abbott: 'Get them out of the way,'* FOX NEWS (Sept. 9, 2021), available at: https://www.foxnews.com/politics/get-them-out-of-the-way-biden-declares-war-on-desantis-and-abbott (last visited Sept. 30, 2021).

[22] *Florida AG Ashley Moody suing Biden administration over COVID-19 vaccine mandate*, WFLA 8 (Sept. 16, 2021), available at: wfla.com/news/florida/florida-ag-ashley-moody-suing-biden-administration-over-covid-19-vaccine-mandate/ (last visited Sept. 30, 2021).

will continue to take legal action against states or elected officials that oppose the vaccine mandate and other measures.[23]

III. THE DOD MANDATE AND ARMED SERVICES GUIDANCE

A. DOD Mandate

46. On August 24, 2021, SECDEF issued the DOD Mandate, directing the Secretaries of the Military Departments "to immediately begin full vaccination of all members of the Armed Forces … who are not fully vaccinated against COVID-19." Ex. 2, DOD Mandate at 1.

47. The only service members expressly exempted are those "actively participating" in vaccine trials. *Id.* "Those with previous COVID-19 infection are not considered fully vaccinated," *id.*, nor are they provided a medical exemption. There is no discussion of exemptions for female service members who are pregnant, nursing or wish to become pregnant, or of the heightened risks of myocarditis or pericarditis for young males that account for a substantial portion of service members. SECDEF further directed that mandatory vaccination "will only use COVID-19 vaccines that receive full licensure from the [FDA], in accordance with FDA labeling and guidance." *Id.*

[23] *See, e.g.,* Collin Binkley, *States banning mask mandates could face civil rights probes*, AP NEWS (Aug. 18, 2021), available at: https://apnews.com/article/joe-biden-health-coronavirus-pandemic-5943b43e54f61861e65d8cb74f3a68f1 (last visited Sept. 30, 2021).

B. AR 40-562 Exemptions

48. AR 40-562 presumptively exempts from any vaccination requirement a service member that the military knows has had a documented previous infection. AR 40-562, para. 2-6(a)(1)(b).[24] AR 40-562 also provides for exemptions for pregnant women. *Id.*, para. 2-6(a)(1)(a). Pregnant service members "may pursue a temporary medical exemption following vaccine counseling," pursuant to AR 40-562, para. 2.6(a). These exemptions apply both for EUA and licensed vaccines.

C. Armed Services Guidance

1. Air Force Guidance

49. On September 3, 2021, the Air Force issued the Air Force Guidance on implementation of the DOD Mandate for Air Force personnel.[25] The Air Force Secretary directed that all active-duty Air Force must be fully vaccinated by November 2, 2021, and all members of the Air National Guard must be vaccinated by December 2, 2021.[26] There is no exemption for previously infected individuals

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[24] The current version of AR 40-562) was signed on Oct. 7, 2013, went into effect on Nov. 7, 2013, and remains in effect today. It applies to all branches of the military. AR 40-562 is also designated as AFI 48-110 (Air Force), BUMEDINST 6230.15B (Marine Corps and Navy), CG COMDETINST, M6230.4G) (Coast Guard).

[25] *See* Ex. 6 Dept. of the Air Force, Deputy Director of Staff for COVID-19, "COVID-19 Mandatory Vaccination Implementation Guidance for Service Members" (Sept. 3, 2021) ("Air Force Guidance").

[26] *See* Secretary of the Air Force Public Affairs, *DAF Announces Mandatory COVID Vaccine Implementation Guidelines for Airmen, Guardians* (Sept. 3, 2021), available at: https://www.af.mil/News/Article-Display/Article/2765008/daf-

like Plaintiffs with natural immunity. *See* Air Force Guidance, § 4.5.1.2.

50. While Air Force Guidance states that "[o]nly an FDA-licensed vaccine may be mandated," *i.e.*, the Comirnaty Vaccine, *id*. § 3.1.3, it goes on to repeat the FDA's (incorrect) claim that the EUA BioNTech Vaccine is "interchangeable" with the licensed product and that "[p]roviders can use doses distributed under the EUA to administer the vaccination series ***as if*** the doses were the licensed vaccine." *Id*., § 3.1.1 (emphasis added); *see also id.*, § 5.3.2.1 (same).

2. Army Guidance

51. On September 14, 2021, the Army announced its implementation guidance.[27] All active-duty Army personnel are required to be fully vaccinated with an FDA-licensed vaccine by December 15, 2021, and all reserve component personnel are required to be fully vaccinated by June 30, 2022. *Id*. There is no exemption for Army personnel with previous infections, nor is there any discussion of exemption for women who are pregnant, nursing or who wish to become pregnant. Soldiers who refuse the vaccine will face "administrative or non-judicial punishment – to include relief of duties or discharge," while officers, commanders, command sergeant majors and sergeant majors "face suspension and relief" of duties. *Id.*

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announces-mandatory-covid-vaccine-implementation-guidelines-for-airmen-guar/ (last visited Oct. 1, 2021).

[27] *See* Ex. 7, U.S. Army Public Affairs, *Army Announces Implementation of Mandatory Vaccines for Soldiers* (Sept. 14, 2021) ("Army Guidance").

3. Navy Guidance

52. On August 30, 2021, the Navy issued implementation guidance,[28] which is also applicable to Marine Corps. All active-duty Navy personnel are required to be fully vaccinated with an FDA-licensed vaccine by November 28, 2021, and all reserve component personnel are required to be fully vaccinated by December 28, 2021. *See id.*, para. 4. The Navy Guidance does not grant, or discuss, any medical exemptions.

53. The Navy Guidance provides that the vaccination order "is a lawful order, and any failure to comply is punishable as a violation of a lawful order under Article 92" of the UCMJ. *Id.*, para. 5. Violations "may result in punitive or adverse administrative action," and the Navy has "the authority to exercise the full range of administrative and disciplinary actions" to enforce compliance. *Id.*

4. Marine Corps Guidance

54. On September 1, 2021, the Marine Corps issued implementation guidance,[29] requiring all active-duty Marines to be fully vaccinated with an FDA-licensed vaccine by November 28, 2021, and all reserve component personnel to be

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[28] *See* Ex. 9, Secretary of the Navy, "2021-2022 Department of Navy Mandatory COVID-19 Vaccination Policy," ALNAV 062/21 (Aug. 30, 2021) ("Navy Guidance").

[29] *See* Ex.8, MARADMIN, "Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components," MARADMINS Number: 462/21 (Sept. 1, 2021) ("Marine Corps Guidance").

fully vaccinated by December 28, 2021. *Id.*, para. 3.a. Individuals with previous COVID-19 infections or positive serology are not exempted. *Id.*, para. 3.j.5. For pregnant women, "[p]er CDC … COVID-19 vaccination is strongly encouraged," although pregnant women may apply for a temporary exemption. *Id.*, para. 3.j.4. The guidance does not authorize exemptions for nursing women or women who wish to become pregnant.

55. The Marine Corps Guidance provides that it "constitutes a lawful general order and any violation of these provisions is punishable as a violation of article 92" of the UCMJ. *Id.*, para. 3.l. The Marine Corps has "the authority to exercise the full range of administrative and disciplinary actions" to enforce compliance. Ex. 9, Navy Guidance, para. 5.

D. Potential Consequences for Non-Compliance

56. Under the UCMJ, a service member who disobeys "any lawful general order or regulation," UCMJ § 892(2), Art. 92(2), faces sanctions up to a court-martial. UCMJ § 892. This punishment may include "dishonorable discharge, forfeiture of all pay and allowances, and confinement for 2 years." *Id.*

57. Dishonorable discharges are typically given for the most serious offenses such as murder, fraud, desertion, treason, espionage, and sexual assault.[30]

[30] *See Manual for Courts-Martial, United States* (2019 ed.), R.C.M. 1003(a)(8) ("A dishonorable discharge should be reserved for those who should be separated under conditions of dishonor, after having been convicted of offenses usually recognized

A dishonorably discharged veteran may also lose all retirement and veterans' benefits and is ineligible for a wide array of other governmental benefits. *Id.* Those with a dishonorable discharge lose important civil and constitutional rights, including the right to bear arms protected by the Second Amendment of the United States Constitution. *Id.*[31]

IV. FEDERAL REGULATORY REGIME FOR LICENSING AND EMERGENCY USE AUTHORIZATION OF VACCINES

A. FDA Vaccine Licensing and Approval

58. The FDCA generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until the FDA has approved the drug or biological product as safe and effective for its intended use. 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C. § 262(a).[32] A vaccine is both a drug and a biological product and is therefore subject to regulation under both the FDCA and the PHSA. *See* 21 U.S.C. § 321(g); 42 U.S.C. § 262(i)(1).

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in civilian jurisdictions as felonies, or of offenses of a military nature requiring severe punishment.").

[31] Dishonorable discharge is not merely a theoretical possibility. Plaintiffs have been verbally threatened with court-martial and dishonorable discharge, along with actual imposition of sanctions and restrictions for vaccine refusal. These commanders have the full support of the Executive, which opposes any limitation on the ability to impose sanctions for vaccine refusal, up to and including dishonorable discharge. *See also supra* 2022 NDAA Statement, note 20, at 4.

[32] *See also* 42 U.S.C. § 262(a)(2)(C)(i)(I) (approval of biological products require demonstration that the product is "safe, potent, and pure"); 21 C.F.R. § 601.2(a) (same). There are no analogous requirements for EUA products.

59. Pursuant to Section 351(a) of the PHSA, 42 U.S.C. § 262(a), the FDA has the authority to approve the sale and manufacture of vaccines and other biologics like the Comirnaty Vaccine. The biologics application addresses not only the safety and efficacy of the product, but also covers specific labeling and manufacturing requirements, including the manufacturing location, process, and storage requirements. EUA products are subject to much lower standards, than those required for licensed products, and they are exempt altogether from certain marketing and manufacturing requirements.

B. "Interchangeable" Biological Products under the PHSA

60. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262,[33] in relation to a "reference product,"[34] which is a biological product licensed under Section 351(a) of the PHSA. 42 U.S.C. § 262(a).[35] For the purposes of determining "interchangeability," the

[33] "Interchangeable" and "interchangeability" are defined as a "biological product" that "may be substituted for the reference product" by health care providers. 42 U.S.C. § 351(i)(3). To meet the standards in 42 U.S.C. § 262(k)(4) ("Safety standards for determining interchangeability"), the "interchangeable" or substitute biological product (i) must be biosimilar to the reference product and (ii) and "can be expected to produce the same clinical result as the reference product in any given patient." 42 U.S.C. § 262(k)(4).

[34] "Reference product" is defined as "the single biological product licensed" under 42 U.S.C. § 262(a) "against which a biological product is submitted" under 42 U.S.C. § 262(k). 42 U.S.C. § 351(i)(4).

[35] These definitions and related provisions were enacted as part of the Biologics Price Competition Act of 2009, which "amends the PHSA and other statutes to create an

"reference product" must be an FDA-licensed product; in this case, the FDA-licensed Comirnaty Vaccine. But the "interchangeable" product, the EUA BioNTech Vaccine, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k), and there is no indication that any such application was ever filed by BioNTech, much less reviewed or approved by the FDA.

C. Emergency Use Authorization Laws and FDA Regulations

61. The FDCA authorizes the FDA to issue an EUA for a medical drug, device, or biologic, where certain conditions have been met. As relevant here, these are that HHS Secretary has declared a public health emergency that justifies the use of an EUA, 21 U.S.C. § 360bbb-3(b)(1), and the FDA finds that "there is no [1] adequate, [2] approved, ***and*** [3] available alternative to the product for diagnosing, preventing, or treating" the disease in question. 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

62. There are significant differences between licensed vaccines and those subject to EUA that render them "legally distinct." Ex. 2, BioNTech Expansion

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abbreviated licensure pathway," under Section 351(k) of the PHSA, 42 U.S.C. § 262(k), "for biological products shown to be interchangeable with an FDA-licensed biological reference product," licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). *See generally* FDA, et al., *Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry* (May 2019), available at: https://www.fda.gov/media/124907/download (last visited Sept. 15, 2021).

Letter, at 2 n.8. First, the requirements for efficacy are much lower for EUA products than for licensed products. EUAs require only a showing that, based on scientific evidence "if available," "it is reasonable to believe," the product "may be effective" in treating or preventing the disease. 21 U.S.C. §360bbb-3(c)(2)(A). Second, the safety requirements are minimal, requiring only that the FDA conclude that the "known and potential benefits … outweigh the known and potential risks" of the product, considering the risks of the disease. 21 U.S.C. §360bbb-3(c)(2)(B). Third, EUA products are exempt from certain manufacturing and marketing standards, enjoy broader product liability protections, and cannot be mandated due to informed consent laws and regulations (subject to the override procedures for service members described below). *See, e.g., Doe v Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004) ("*Rumsfeld II*") (granting injunction against DOD anthrax vaccine mandate for EUA vaccine).

63. The public health emergency declaration that justifies the use of an EUA for a product "shall terminate upon the earlier of … a change in the approval status" of the EUA product. 21 U.S.C. § 360bbb-3(b)(2)(A)(ii). Thus, the approval, or licensing, of a vaccine for a given indication terminates the EUA for that vaccine. The requirements for licensing and emergency use authorization are mutually exclusive; the same product—or same vial of vaccine—cannot be concurrently

subject to an EUA and licensed for the same indication or use, under distinct regulatory regimes.[36]

D. Informed Consent Requirements for EUA Products

64. The FDA's grant of an EUA is subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the product." FDCA § 564(e)(1)(A)(ii)(III); 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).[37] The FDA imposes and enforces the "option to accept or refuse" condition by requiring distribution to potential vaccine recipients a Fact Sheet that states, "It is your choice to receive or not receive [the vaccine]."

65. The DOD may override service members' informed consent rights, provided that it complies with the requirements of 10 U.S.C. § 1107 (investigational

[36] *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020) (holding that the FDA's determination that it could choose to regulate a product as either a drug or a device, or both, as arbitrary and capricious and exceeding its statutory authority).

[37] The norm of informed consent has been "firmly embedded" in U.S. law and FDA regulations for nearly 60 years. *Adullahi v. Pfizer, Inc*., 562 F.3d 163, 182 (2nd Cir. 2009). Congress first enacted this requirement in 1962 drawing on the Nuremberg Code and the Helsinki Declaration, "which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation." *Adullahi*, 562 F.3d at 182 (citation omitted). Informed consent requirements are a cornerstone of FDA rules governing human medical experimentation. *See, e.g.,* 21 C.F.R. §§ 50.20, 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-117.

new drugs) or § 1107a (EUA products).[38] The procedures to override service members' informed consent rights have not been followed or implemented by the DOD. Neither the DOD nor the Armed Services acknowledge any duty to invoke these procedures because, in their view, Plaintiff service members do not have any rights to informed consent or to refuse vaccination because Comirnaty has been licensed.

E. FDA Emergency Use Authorizations for COVID-19 Vaccines

66. The FDA issued an EUA for the BioNTech Vaccine on December 11, 2020, for the Moderna Vaccine on December 18, 2020, and for the Janssen Vaccine on February 27, 2021. The FDA granted an EUA for the BioNTech Vaccine based on approximately two months of safety and efficacy data.[39]

67. For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in Section 564(e)(1)(A)(ii)(III) in each letter granting the EUA by requiring that FDA's "Fact Sheet for Recipients and

[38] *See* Exec. Order No. 13,139, 64 Fed. Reg. 192, "Improving Health Protection of Military Personnel Participating in Particular Military Operations" (Oct. 5, 1999) (informed consent override procedures under 10 U.S.C. § 1107); DOD Instruction 6200.02, "Application of Food and Drug Administration Rules to Department of Defense Force Health Protection Programs" (Feb. 27, 2008) (override procedures under 10 U.S.C. § 1107a).

[39] *See generally* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product: Review Memorandum* (Dec. 11, 2020), available at: https://www.fda.gov/media/144416/download (last visited Oct. 1, 2021).

Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet includes the statement that it is your choice to receive or not receive the vaccine.

F. BioNTech Vaccine EUA Expansion

68. The requirements for licensing and emergency use authorization are mutually exclusive. The same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use, under distinct regulatory regimes. Yet that is precisely what the FDA has done by: (1) simultaneously licensing Comirnaty Vaccine and re-issuing the EUA for the BioNTech Vaccine for the same indication (individuals 16 years or older); (2) re-issuing and expanding the existing BioNTech Vaccine EUA for children of 12-15 years of age and permitting the licensed Comirnaty Vaccine to be used for this group; and (3) finding that the EUA BioNTech Vaccine and licensed Comirnaty Vaccine can be used "interchangeably" and may be substituted for each other. Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

69. First, the approval of Comirnaty should have automatically terminated the EUA for that use. *See* 21 U.S.C. 360bbb-3(b)(2)(A)(ii). The FDA chose to ignore this statutory requirement.

70. Second, to grant an EUA, or extend an existing EUA, the FDA must find that there is no alternative that is (1) adequate, (2) approved, and (3) available. 21 U.S.C. § 360bbb-3(c)(3); *see also* Ex. 5, BioNTech Expansion Letter at 5. All

three requirements must be met. Comirnaty is approved and presumably adequate, so the FDA's EUA re-issuance and expansion is based on that fact that the licensed vaccine is "not … available" in sufficient quantities. *Id.* at 5 n.9. "Not available" is a binary requirement; an alternative either is or is not available; there is no room in the statute for the FDA to add a third option – not available in sufficient quantity – for the purpose of enabling vaccine mandates.

71. The FDA licensed a product that is not available, and then informed the general public that the EUA-labeled and manufactured product can be used "interchangeably," or substituted, for the licensed product.[40] The FDA provides no justification for ignoring and nullifying these express statutory requirements of the FDCA, which also has the effect of nullifying Plaintiffs' rights to informed consent and to refuse the administration of an experimental vaccine.

V. FDA COMIRNATY APPROVAL

A. FDA Guidance on Testing and Review of COVID-19 Vaccines

72. In June 2020, HHS, FDA and the Center for Biologics Evaluation and Research ("CBER") issued guidance to vaccine developers on clinical and non-

[40] The FDA BioNTech EUA Expansion letter appears to authorize injection from an EUA-labeled and manufactured vial for the same indications as the licensed product, namely, to individuals 16 years or older pursuant to a mandate; conversely, it would authorize off-label use of Comirnaty Vaccine manufactured and labeled in compliance with the BLA to be administered to a 12-year old, an indication for which Comirnaty is not licensed.

clinical testing and the procedures the FDA intended to apply in evaluating and approving COVID-19 vaccines.[41] The June 2020 Industry Guidance included a number of recommendations that ultimately were not followed, in particular: (1) the inclusion in clinical trials of individuals with previous COVID-19 infections, *id.* at 11; (2) the inclusion of pregnant women, *id.*; and (3) the use of clinical trials lasting "***at least*** one to two years," *id.* at 12 (emphasis added). The FDA also indicated its intent to follow its standard procedure for clinical trial results to be reviewed by the Advisory Committee.

B. Citizen Petition & FDA Response

73. Many of the arguments made by Plaintiffs regarding the need to study special populations, *i.e.,* those with natural immunity, pregnant/nursing women, etc. (or else provide contraindications), and the numerous procedural, scientific, and evidentiary defects in the FDA's review and approval of the Comirnaty Vaccine were made in a Citizen Petition submitted by the Coalition Advocating for Adequately Licensed Medicines on July 23, 2021 in Docket No. FDA-2021-P-0786. *See* Ex. 11 ("Citizen Petition"). The FDA denied the Citizen Petition on August 23, 2021. *See* Ex. 12 ("FDA CP Response"), the same day that it approved Comirnaty.

[41] *See* Ex. 10, HHS, FDA & CBER, Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry (June 2020) ("June 2020 Industry Guidance"), available at: https://www.fda.gov/media/139638/download (last visited Sept. 22, 2021).

C. FDA Comirnaty Approval and BioNTech EUA Expansion Letters

74. On August 23, 2021, the FDA approved the May 18, 2021, Comirnaty application for individuals 16 years or older. Also on August 23, 2021, the FDA re-issued the EUA for the BioNTech Vaccine for individuals 16 years or older and for children aged 12 to 15 years, and expanded the EUA to cover a third "booster" shot for certain groups. The FDA Comirnaty Approval and BioNTech EUA Expansion thus licensed a vaccine and continued an existing EUA for the same indication (individuals 16 years or older).

75. The FDA has incorrectly asserted that the EUA BioNTech Vaccine and the conditionally approved Comirnaty Vaccine can be used "interchangeably." Ex. 5, BioNTech EUA Expansion Letter at 2 n.8. As explained above, this statement is contradictory and incorrect insofar as it suggests that an EUA Vaccine, manufactured and labeled in accordance with the EUA, may be treated as a licensed product.[42] The fact that other agencies have seized on this language to justify mandates, *see* Ex. 6, Air Force Guidance, § 3.1.1, (authorizing providers to treat an

[42] Conversely, it suggests that the Comirnaty Vaccine can be used for "off-label" uses under the EUA, *e.g.*, for a child under 16 or for a third "booster" dose for which there is no clinical trial data available. *See* Ex. 5, BioNTech EUA Expansion Letter at 2 ("authoriz[ing] use of the Comirnaty (COVID-19, mRNA) under this EUA for certain uses that are not included in the approved BLA" for the licensed product).

EUA vaccine "as if" it were the licensed product), indicates that this was the intended result.

76. The FDA appears to acknowledge that the EUA BioNTech Vaccine and the conditionally licensed Comirnaty Vaccine are not in fact "interchangeabl[e]." The Comirnaty Approval Letter approves the sale of Comirnaty Vaccine, as well as the specific manufacturing facilities, processes, ingredients, storage, and distribution requirements that were not addressed in the BioNTech Vaccine EUA. For example, the Comirnaty Approval Letter requires FDA approval for release of Comirnaty lots manufactured in accordance with the terms of the license.[43] Given the differences in manufacturing between EUA and licensed vaccines, the FDA also required BioNTech to identify specific lots of EUA-labeled and manufactured BioNTech Vaccines that BioNTech deemed BLA-compliant for FDA review and release. *See* Ex. 4, Comirnaty SBRA at 27 (Section 10.a "Identification of BLA Lots").

77. The Comirnaty Vaccine is not widely available due to limited supply. *See* Ex. 5, BioNTech EUA Expansion Letter at 5 n.9. This has been affirmed by recent media reports,[44] and supports the conclusion that the DOD and other

[43] *See* Ex. 3, Comirnaty Approval Letter at 2 ("FDA Lot Release;" "You may not distribute any lots of the licensed product [i.e., Comirnaty Vaccine] until you receive a notification of release from the Director [CBER].").

[44] *See, e.g.,* Zachary Steiber, *Newly Approved COVID-19 Vaccine Not Yet Available in US*, EPOCH TIMES (Sept. 3, 2021), available at:

employers intend to mandate vaccination using an the EUA vaccine (BioNTech Vaccine), rather than the licensed Comirnaty Vaccine.

D. Procedural and Substantive Deficiencies in FDA Comirnaty Review and Approval Process.

78. The FDA claims that the Comirnaty Vaccine approval followed its "standard process for reviewing the quality, safety, and effectiveness of medical products,"[45] but this statement is belied by its contemporaneous statements and the deficient process it followed. In its August 23, 2021, press conference, the FDA Acting Commissioner Woodcock conceded that the FDA followed an "unprecedented timeline," Coleman, *supra* note 10, in approving the Comirnaty application in just over three months. It did so by skipping, or failing to require, the procedures and clinical trial data needed to assess Comirnaty's safety and efficacy.

1. The FDA Permitted Exclusion of "Special Populations."

79. Neither the BioNTech Vaccine nor the Comirnaty Vaccine has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, the trials conducted so far have specifically excluded

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https://www.theepochtimes.com/newly-approved-covid-19-vaccine-not-yet-available-in-us_3976794.html/amp (last visited Sept. 7, 2021).

[45] FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021) ("FDA Comirnaty Press Release"), available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Sept. 22, 2021).

survivors of previous COVID-19 infections.[46] The clinical trials also did not include any pregnant or lactating women.[47] The FDA instead relied solely on rat studies in its approval of Comirnaty for these populations.[48] The clinical trials also did not include participants from and/or provide sufficient data for other "special populations" such as those with autoimmune disorders or hematological conditions, children, and frail elderly populations. *See* Ex. 17, Ruby Affidavit at ¶ 15.

80. The Comirnaty application also skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. *See id.* at ¶ 13. In other words, it is unknown whether or not COVID-19 vaccines will change human genetic material, cause birth defects, reduce fertility, or cause cancer.

2. The FDA Relied on Interim Results for Limited and Self-Selected Sample.

81. While the Phase 3 clinical trials included a large and statistically significant number of participants, the full sample trial was truncated in

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[46] *See* Fabio Angeli, *SARS-CoV-2 vaccines: Lights and Shadows*, EUROPEAN J. OF INTERNAL MEDICINE 2021;88:1-8.

[47] *See* Sandra Kweder, MD, et al., *Global Regulators Envision Paradigm Shift Toward Inclusion of Pregnant and Breastfeeding Women in Clinical Research for Medicines and Vaccines*, FDA News Releases (July 19, 2021), available at: https://www.fda.gov/news-events/fda-voices/global-regulators-envision-paradigm-shift-toward-inclusion-pregnant-and-breastfeeding-women-clinical (noting that no pregnant or lactating women were included in any COVID-19 vaccine trials).

[48] *See* Ex. 13, FDA, "Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)," at 33 (Aug. 23, 2021) (emphasis added) ("BioNTech/Comirnaty Vaccine Fact Sheet").

unprecedented fashion. It was only followed for ***two months*** (*i.e.*, largely the same trials and participants as used to grant the initial EUA for the BioNTech Vaccine) instead of the FDA's recommended period of at least ***one to two years*** set forth in the June 2020 Industry Guidance. Further, the median period that trial participants were followed was four months, and about one-fourth were covered for six months. *See supra* FDA Comirnaty Press Release, note 4. Because clinical trials typically run for years, rather than a few months, the FDA has acknowledged that "[i]nformation is not yet available about potential long-term health outcomes," *id.*, and it has conditioned Comirnaty approval on the completion of at least nine additional clinical trials running through 2025 (none of which specifically address previously infected individuals with natural immunity).

82. The FDA fails to acknowledge, however, that the results of the trials beyond the first two months are of questionable (or perhaps negligible) validity due to fundamental methodological error that infect all results and undermine any conclusions that can be drawn from them. In its May 18, 2021 application,[49] which included interim six-month safety and efficacy data for Phase 3 clinical trials, Pfizer-BioNTech explained that study participants were given the option to be "unblinded"

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[49] *See* Stephen J. Thomas, MD, *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, medRxiv Preprint (July 28, 2021), available at: https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf (last visited Sept. 22, 2021).

– to learn whether they had taken the experimental BioNTech Vaccine or the placebo – and if they had taken the placebo, to take the BioNTech Vaccine. As a result, only approximately 7% of study participants were blinded after six months. *Id.* at 5. This "unblinding" converted a randomized, controlled clinical trial into a "modified-open label, observational variable dose trial with no informed consent." *See* Ex. 17, Ruby Affidavit at ¶ 12. Accordingly, the FDA's statements that the Comirnaty approval was based on "randomized, controlled, blinded ongoing clinical trial of thousands of individuals," *see supra* FDA Comirnaty Press Release, note 4, is severely and intentionally misleading.

83. The problem with the unblinding is not simply that the data available after two months covers a smaller number of participants. Instead, it introduces a number of methodological errors that cannot be corrected or adjusted *post hoc*; it infects all results. First, the unblinding introduces an incurable self-selection bias. Second, it effectively eliminates the "control" group, and therefore any randomization. Third, there is no information provided on the demographic characteristics of those who were unblinded vs. those who remained blinded (race, sex, age, membership in "special populations," previous infection status, etc.), whether they received the vaccination or the placebo, or any self-reported reasons for unblinding (e.g., the presence or absence of side effects or adverse reactions).

Fourth, it almost certainly unbalanced the 1:1 matching at the heart of the study design and the numbers of participants in the various sub-groups under examination.

3. The FDA Ignored Evidence of Serious Adverse Effects and Failed to Convene Advisory Committee.

84. Despite the thousands of deaths and serious injuries self-reported through VAERS, *see infra* Section VI.C, the FDA chose not to follow its earlier industry guidance, or their standard practice, to refer this BLA for Advisory Committee review and the consequent opportunity for public notice and comment. *See* Ex. 4, Comirnaty SBRA at 27 ("FDA did not refer this application to the [Advisory Committee] because … this BLA did not raise concerns or controversial issues that would have benefitted from an advisory committee action.").

85. The FDA knew that the licensing of the Comirnaty Vaccine would be used to enable vaccine mandates not only by employers, but also that vaccination would become a condition to go to school, worship, travel by air or across state lines, or even to buy groceries in many areas. It is hard to imagine an issue that could be more "controversial" than the imposition of vaccine mandates that would bar at least a third of Americans from participating in the Nation's economic and social life. The FDA avoided its obligations under the FDCA and the APA to explain its decision, and to provide the public with an opportunity to comment on a matter of such

momentous importance to the health and constitutional rights of hundreds of millions of U.S. citizens.

VI. SAFETY AND EFFICACY DATA FOR COVID-19 VACCINES

A. Novel Technology

86. COVID-19 vaccines employ novel technology, namely, mRNA delivered by nanolipids. COVID-19 vaccines are considered gene-based vaccines or vaccines produced from gene therapy molecular platforms, whose safety and efficacy has not been fully assessed. This is unlike all other vaccines where there is a set amount of antigen or a live-attenuated virus in the vaccine.

87. According to the FDA, there is insufficient data to know whether the COVID-19 Vaccines actually prevent asymptomatic infection or prevent transmission of SARS-CoV-2, the virus that causes COVID-19. Recent data from the U.S.[50] and abroad[51] suggest that they do not prevent either.

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[50] *See* Catherine M. Brown, DVM, et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT Aug. 2021;70(31): 1059-1062 (Aug. 6, 2021) available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w#suggestedcitation (last visited Sept. 30, 2021).

[51] *See* Nathan Jeffay, *Israeli, UK data offer mixed signals on vaccine's potency against Delta strain*, THE TIMES OF ISRAEL (July 22, 2021), available at: https://www.timesofisrael.com/israeli-uk-data-offer-mixed-signals-on-vaccines-potency-against-delta-strain/ (last visited Sept. 2, 2021); Ian Sample, *Scientists back Covid boosters as studyfinds post-jab falls in antibodies*, THE GUARDIAN (July 22, 2021), available at: https://www.theguardian.com/world/2021/jul/22/uk-scientists-

88. These vaccines were only tested on humans for a limited period of time. For example, the Comirnaty Vaccine Phase 2 and Phase 3 trials only covered the full sample for approximately two months, and a much smaller sample for up to six months. *See infra* Section V.D. Accordingly, there is absolutely no knowledge whatsoever of the long-term efficacy or long-term safety of these vaccines, which "is not proven." *Klaassen*, 2021 WL 3073926, at *12. Clinical trials for these vaccines are scheduled to continue through 2023 to 2025. *See* Ex. 3. Because these vaccines have only been used by the public for less than a year, it is impossible to assess or know fully the safety and efficacy of these vaccines, their necessity, and whether their benefits outweigh the risks.

B. Waning Efficacy and Need for "Booster" Shots

89. Recent studies indicate that the efficacy and protection of the BioNTech Vaccine drops off significantly over time, particularly after the six-month period on which the FDA relied in conditionally approving the Comirnaty Vaccine. For example, recent and well-publicized studies from Israel found that the BioNTech Vaccine's effectiveness decreased from over 90% to 39% after six months for infections and 40.5% for symptomatic cases.[52] Plaintiffs are not aware of any studies

back-covid-boosters-as-study-finds-post-jab-falls-in-antibodies (last visited Sept. 2, 2021).

[52] *See* Ex. 14, Israel Ministry of Health Presentation (July 23, 2021), available at: https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-

contradicting the Israeli studies. In fact, these study results are the reason Israel is already requiring a third booster shot (and is considering a fourth).[53]

90. At the September 17, 2021 FDA Advisory Committee meeting to consider approval of booster shots, Sara Oliver MD, MSPH presented an overview of studies demonstrating the rapidly declining efficacy of the Pfizer-BioNTech vaccine, in the United States and abroad.[54] Several U.S. studies found that the efficacy of COVID-19 vaccines dropped from over 90% to as 42% (with a median of roughly 65%) over an up to six-month period, with the steepest drops found in the studies with the longest study periods; the only study limited to the Pfizer-BioNTech

committee/he/files_publications_corona_two-dose-vaccination-data.pdf (last visited Sept. 23, 2021) (summarizing six-month efficacy data for Pfizer-BioNTech vaccine in Israel); *see also* Rory Jones & Dov Lieber, *Pfizer COVID-19 Vaccine Is Less Effective Against Delta Infections but Still Prevents Serious Illness, Israel Study Suggests*, WALL STREET J. (July 23, 2021), available at: https://www.wsj.com/articles/pfizer-covid-19-vaccine-is-less-effective-against-delta-infections-but-still-prevents-serious-illness-israel-study-shows-11627059395 (last visited Sept. 22, 2021).

[53] *See* Rosella Tercatin & Maayan Jaffe-Hoffman, *COVID-19 Boosters Expanded to 40 Years Old and Up*, JERUSALEM TIMES (Aug. 20, 2021), available at: https://www.jpost.com/health-science/covid-israel-registers-600-serious-patients-3rd-vaccine-to-be-expanded-677144 (last visited Sept. 4, 2021).

[54] *See* Ex. 15, Sara Oliver MD, MSPH, *Updates to COVID-19 Epidemiology and COVID-19 Vaccines*, Presentation to September 17, 2021 VRBPAC Meeting (Sept. 17, 2021) ("Oliver FDA Presentation"), available at: https://www.fda.gov/media/152243/download (last visited Sept. 22, 2021).

vaccine got the low score of 42%.[55] Dr. Oliver also presented studies finding a steep decline in efficacy 15%-35% for the pre-Delta vs. the Delta variant. *Id.*, Slide 20. She also presented a number of international studies showing even sharper decreases in efficacy in countries such as Qatar where the Delta variant was prevalent at an earlier date. *Id.* at 21.[56]

91. The Administration announced its intention to make booster shots available to all adult U.S. citizens who are already fully vaccinated by September 20, 2021. In its September 17, 2021 meeting, the FDA Advisory Committee rejected this deadline, and instead recommended booster shots initially for elderly and at-risk individuals; the FDA implemented this recommendation on September 22, 2021.[57]

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[55] *See id.*, Slide 15 (citing A. Puranik et al., *Comparison of two highly effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv2021.08.06.21261707*).

[56] Despite this information, the CDC is inexplicably not tracking "breakthrough" infections of vaccinated people. *See, e.g.,* Rachel Roubein & David Lim, *CDC Under Fire for Decision to Limit Tracking of COVID-19 Cases in Vaccinated People*, POLITICO (July 30, 2021), available at: https://www.politico.com/news/2021/07/30/pressure-cdc-breakthrough-cases-501821 (last visited Sept. 19, 2021). This would have provided essential information regarding the long-term efficacy of Comirnaty and other COVID-19 vaccines. Several other countries have continued to track breakthrough infections, which has revealed the rapidly declining efficacy of COVID-19 vaccines and enormous increases in infections of the most vaccinated populations, leading many to concern that the vaccines are enhancing the disease instead of protecting against it.

[57] *See* FDA, News Release, *FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations*, FDA News Release (Sept. 22, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-

This debate demonstrates that there is no scientific consensus, or certainty, on the long-term efficacy, or even the proper dosage of the Comirnaty Vaccine. Perhaps more importantly, it suggests that, if the FDA had followed normal procedures of convening an Advisory Committee meeting, it may have had the chance to consider a wider range of views and evidence on Comirnaty's safety and efficacy, and delayed its approval, or limited it to groups for which there was clinical trial data required to fulfill its duty to engage in reasoned decision-making.

92. The debate over booster shots and declining efficacy also resulted in the resignation of the two of the FDA's most senior vaccine leaders, purportedly due to improper political interference in the accelerated approval of COVID-19 vaccines and for "booster" shot requirements.[58] Further, a former FDA staffer stated that Gruber and Krause are departing because they are frustrated that CDC and the ACIP committee are involved in decisions that they think should be up to the FDA. *Id.*

93. Based on the limited efficacy of the COVID-19 vaccines and their

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authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations (last visited Sept. 22, 2021).

[58] Marion Gruber, Director of the FDA's Office of Vaccines Research and Review and 32-year veteran of the agency will leave at the end of October, and OVRR deputy director Phil Krause, who has been at the FDA for more than a decade, will leave in November, 2021. *See* Sarah Owermohle, *Biden's Top-Down Booster Plan Sparks Anger at FDA*, POLITICO (Aug. 31, 2021) available at: https://www.politico.com/news/2021/08/31/biden-booster-plan-fda-508149 (last visited Sept. 22, 2021).

inability to prevent re-transmission, the CDC abandoned any pretense that the COVID-19 vaccines can prevent disease or its spread, and moved the goalposts to merely providing "protection." In fact, the COVID-19 vaccines may be more appropriately classified as therapeutics than vaccines. Proving this point is the recent decision by the CDC to change the definition of "vaccine" from a product that will "produce immunity"[59] (the definition from 2015 – August 2021) to one that will "produce protection" (September 2021).[60]

94. There is simply no data available – nor could there be – that Comirnaty or other COVID EUA Vaccines can produce long-term immunity or prevent transmission, and accordingly, provide the public health (as opposed to individual health) benefits on which the DOD Mandate and other mandates are based. There is no substitute for time when determining the long-term safety and efficacy of vaccines. This Court should not defer to the FDA's procedurally and substantively

[59] CDC, *Vaccines and Immunizations: Definition of Terms* (Aug. 26, 2021), available at: http://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Sept. 18, 2021) (defining "vaccine as "[a] product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.").

[60] CDC, *Vaccines and Immunizations: Definition of Terms*, available at: https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Sept. 18, 2021) (defining "vaccine" as [a] preparation that is used to stimulate the body's immune response against diseases.").

deficient determination.

95. Finally, some Plaintiffs possess natural immunity, so neither they nor the community would benefit from them receiving the vaccine. Moreover, as discussed, it is evident that the COVID-19 vaccines are less effective at preventing infection (and thereby spread of the disease) than natural immunity is at preventing re-infection. Accordingly, there is no public health justification for the DOD Mandate.

C. VAERS Data on COVID-19 Vaccine Injuries and Side Effects

96. The VAERS data reveal unprecedented levels of death and other adverse events since the FDA issued EUAs for the three COVID vaccines. The reported death toll is greater than the combined death toll of all other federally-recommended vaccines administered in the United States since 1990 (totaling 5,018).[61] Similarly, according to VAERS, these three vaccines have also caused nearly as many hospitalizations (29,079 vs. 37,747) and severe life-threatening events (8,056 vs. 37,747) as the combined total of all other vaccines administered since they began tracking this information. *Id.* These adverse events include life-threatening anaphylaxis, myocarditis and pericarditis (heart inflammation), blood

[61] *See* VAERS Analysis, *VAERS Summary for COVID-19 Vaccines Through 8/27/2021*, available at: https://vaersanalysis.info/2021/09/03/vaers-summary-for-covid-19-vaccines-through-8-27-2021/ (last visited Sept. 4, 2021).

clotting disorders, cardiac disorders, miscarriages, Bell's Palsy, Guillain-Barré syndrome and death.[62]

97. It is well known that VAERS captures only a fraction of the actual injuries caused by vaccines. In fact, a 2010 federal study commissioned by HHS and performed by Harvard consultants on behalf of the Agency for Healthcare Research and Quality found that "fewer than 1% of vaccine adverse events" are ever reported to VAERS.[63] As a result, the COVID-19 vaccines are likely more dangerous – and more deadly – than reported.

D. Evidence of Natural Immunity for Those with Previous Infections

1. Israeli Study

98. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. A study conducted in Israel (the "Israeli Study"), one of the

[62] VAERS also collects data worldwide. As of September 9, 2021, VAERS had collected the following reports of adverse reactions to COVID-19 vaccines: (1) 675,591 total reports; (2) 14,506 deaths; (3) 58,440 hospitalizations; (4) 77,919 urgent care visits; (5) 106,184 office visits; (6) 5,783 anaphylaxis; (7) 7,911 Bell's Palsy; (8) 1,757 Miscarriages; (9) 6,422 Heart Attacks; (10) 5,371 Myocarditis/Pericarditis; (11) 18,439 Permanently Disabled; (12) 2,910 Thrombocytopenia/ Low Platelet; (13) 14,594 Life Threatening; (14) 27,336 Severe Allergic Reaction; and (15) 7,810 Shingles. *See id.*

[63] *See* Ross Lazarus, MBBS, MPH, MMed, GDCompSci, *Electronic Support for Public Health—Vaccine Adverse Event Reporting System*, available at: https://rickjaffeesq.com/wp-content/uploads/2021/02/r18hs017045-lazarus-final-report-20116.pdf.

most vaccinated countries on Earth, is the most recent – with data collected through August 14, 2021 – and the "largest real-world observational study comparing natural immunity," gained from COVID-19 infection, and "vaccine-induced immunity" from the BioNTech Vaccine.[64]

99. The Israeli Study concluded that: "***natural immunity confers longer lasting and stronger protection against infection***, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2" compared to BioNTech vaccine immunity. *Id.* Specifically, fully vaccinated individuals with no previous infections had a "statistically significant 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection [with the Delta variant] as opposed to reinfection (P<0.001)" of those previously infected. *Id.* at 12.[65] With respect to symptomatic disease, the fully vaccinated had a "27.02-fold risk (95% CI, 12.7 to 57.5) symptomatic breakthrough infection as opposed to reinfection (P<0.001)." *Id.* at 12-13.[66]

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[64] Sivan Gavit, MD MA, *et al.*, *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections versus Breakthrough Infections* at 15, medRxiv Preprint (Aug. 25, 2021), available at: https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

[65] These results were obtained after adjusting for co-morbidities and matching the time of first event (*i.e.*, administration of second dose for those in Group 1 or the time of documented infection for those in Group 2). *Id.* at 9.

[66] The Israeli Study also found that, without matching for time of first event, there was still a statistically significant differences (P<0.001) between Group 1 and Group 2: Group 1 "had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough

2. Cleveland Clinic Study

100. These results are consistent with an earlier study by doctors and researchers from the renowned Cleveland Clinic.[67] The Cleveland Clinic Study included 1,359 previously infected individuals who did not take any COVID-19 vaccine, and found that "[n]ot one of the 1,359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study." *Id.* at 2.

101. With respect to the benefits of vaccination, the Cleveland Clinic Study found that "vaccination was associated with a significantly lower risk of SARS-CoV-2 infection among those not previously infected (HR 0.031, 95% CI 0.015 to 0.061)," but that vaccination did not lower the risk of re-infection "among those previously infected (HR 0.031, 95% CI 0 to Infinity)." *Id.* The Cleveland Clinic Study concluded that previously infected individuals are therefore "unlikely to benefit from COVID-19 vaccination." *Id.*

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infection" and "a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease" compared to the risk of reinfection for those in Group 2. *Id.* at 13.

[67] *See* Nabin K. Shrestha, MD, MPH, *et al.*, *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, medRxiv preprint (June 19, 2021) ("Cleveland Clinic Study"), available at: https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.full.pdf. The Cleveland Clinic Study examined 52,238 employees of the Cleveland Clinic Health System for a five-month period beginning in December 2020.

3. Longitudinal Study

102. The more robust response of natural immunity to mutated forms of COVID is supported by the results of a longitudinal analysis of 254 patients over eight months.[68] This study found that SARsS-CoV-2 infection produces "broad and effective immunity" that "may persist long-term in recovered COVID-19 patients."

E. Alternative and Effective Treatments for COVID-19

103. There are now well-studied, safe and reliable alternatives to vaccination for prevention and treatment of COVID-19, including, but not limited to Ivermectin, Methylprednisolone, Fluvoxamine, Hydroxychloroquine, Vitamin C, Vitamin D3, Zinc, Melatonin, Aspirin, corticosteroids, monoclonal antibodies, and other accessible therapies. Merck recently announced a new COVID-19 treatment, an oral antiviral pill that dramatically reduces risks of hospitalization and death.[69]

104. For example, Ivermectin was rejected by the FDA, despite having significantly more peer reviewed studies, forty-four (44) peer reviewed studies, and

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[68] Kristen W. Cohen, et al., *Longitudinal Analysis Shows Durable and Broad Immune Memory after SARS-CoV-2 Infection with Persisting Antibody Responses and Memory B and T Cells*, CELL REPORTS MEDICINE 2, 100354 (July 20, 2021), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8253687/ (last visited Sept. 22, 2021).

[69] *See, e.g.,* Robert F. Service, *"Unquestionably a Game Changer!" Antiviral Pill Cuts COVID-19 Hospitalization Risk*, SCIENCE (Oct. 1, 2021), available at: https://www.science.org/content/article/unquestionably-game-changer-antiviral-pill-cuts-covid-19-hospitalization-risk (last visited Oct. 4, 2021).

thirty-two (32) double-blind clinical trials showing substantially higher efficacy than treatments such as Remdesivir.[70] Ivermectin is used over the counter for COVID in many countries and regions with excellent reported treatment success, such as India. The drug's safety has been established with nearly four billion human doses used, and the drug is on the World Health Organization's list of essential drugs.

VII. PLAINTIFFS WILL EXPERIENCE CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF THE DOD VACCINE MANDATE

105. Natural Immunity Plaintiffs, WOBCP Plaintiffs and other Plaintiffs have real, substantial, and legitimate concerns about taking a COVID-19 vaccine in light of and the potential for short- and long-term side effects as well as potential adverse reactions from the vaccines themselves.

106. All Plaintiffs will face adverse employment or disciplinary actions, up to and including termination, separation, dishonorable discharge, court martial, loss of post-separation benefits, and permanent damage to their reputation and employment prospects resulting from a court martial and/or dishonorable discharge.

107. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Rumsfeld I*, 297 F.Supp.2d at 135. The injury is exacerbated by the fact that the government not only seeks to deprive

[70] *See* Ex. 16, *FDA COVID-19 Drug Approval Process Remdesivir vs Ivermectin*.

them of their informed consent rights both through deception and coercion, but also to take their freedom and livelihoods for having the temerity to exercise the rights granted to them by statute and the U.S. Constitution.

FIRST CAUSE OF ACTION
DOD VIOLATIONS OF ADMINISTRATIVE PROCEDURE ACT

108. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

109. The DOD Mandate and the Armed Services Guidance violates AR 40-562, which expressly provide a presumptive medical exemption for service members with natural immunity gained through previous infections. See AR 40-562, para. 2-6(a)(1)(b)s. The DOD and the Armed Services have also violated the Administrative Procedures Act insofar as they have effectively modified, repealed or nullified AR 40-562, a legislative rule, without instituting the required notice-and-comment rulemaking proceeding to modify or repeal the regulation. The DOD Mandate modifies AR 40-562 insofar as it: (1) imposes an entirely new vaccine requirement not found in the regulation; and (2) eliminates a medical exemption for natural immunity to which service members could otherwise qualify.

110. Where, as here, an agency amends a legislative rule, effecting a substantive change in the regulation, the agency must institute a new "notice and comment" rulemaking under 5 U.S.C. § 553. *See, e.g., U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34-35 (D.C. Cir. 2005). Further, by failing to institute the required

rulemaking process, the DOD's action violated the Administrative Procedures Act because its actions were made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

111. The DOD Mandate and the Armed Services Guidance also must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(A), insofar as they impose a sweeping vaccine mandate without any explanation or justification for their action or the legal basis thereunder; any findings of facts or analysis supporting their determination; and are based on patent misrepresentations of the law (in particular, that an EUA product may be administered "as if" it were the licensed product). The DOD Mandate's sole justification or explanation is a conclusory statement that the SECDEF has "determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people." Ex. 2, DOD Mandate at 1. Given that the DOD Mandate was issued on the very next day after the FDA Comirnaty Approval, there could not have been any meaningful consideration or analysis of the Comirnaty, the FDA's analysis, the legal consequences or alternatives to compliance with AR 40-562, nor is there any indication that the DOD and SECDEF engaged in the careful and the reasoned decision-making that the APA requires and that service members deserve. *See, e.g., Bayer Healthcare, LLC v. FDA*, 942 F.Supp.2d 17, 25 (D.D.C. 2013).

112. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unwanted, unnecessary and unproven vaccine—pursuant to an unlawful order that is itself based on an invalid FDA approval or EUA—or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

SECOND CAUSE OF ACTION
VIOLATION OF INFORMED CONSENT RIGHTS
10 U.S.C. §§ 1107 AND 1107a AND 21 U.S.C. 360bbb-3

113. Plaintiffs reallege the facts in Paragraphs 1 through 1047 as if fully set forth in this Count.

114. The DOD Mandate and the Armed Services Guidance violate numerous federal laws and implementing rules and regulations governing EUA products and informed consent rights, *see* 10 U.S.C. §§ 1107 and 1107a and 21 U.S.C. § 360bbb-3, to the extent that the DOD or the Armed Services mandate the EUA BioNTech Vaccine, or permit the administration of the EUA vaccine pursuant to the DOD Mandate.

115. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* Ex. 2, DOD Mandate at 1, the Armed Services Guidance expressly states that the EUA BioNTech Vaccine may be administered "as if" it were the licensed Comirnaty Vaccine pursuant to the DOD Mandate. *See, e.g.,* Ex. 6, Air Force Guidance, § 3.1.1; *see also* Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

The EUA and the licensed product are, however, "legally distinct" in that the EUA BioNTech Vaccine is subject to the laws governing EUA products, including the right to informed consent, while the Comirnaty Vaccine is subject to the laws governing FDA-licensed products; these two regimes are mutually exclusive.

116. Defendants' position is based on willful misrepresentations of the law—that a product may simultaneously be both an EUA and licensed vaccine for the same indication, and that an EUA vaccine may be mandated "as if" it were the licensed product—for the purpose of deceiving and coercing service members to forfeit their statutory rights to informed consent and to refuse an unlicensed vaccine.

117. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unwanted, unnecessary, and unproven vaccine, based on an invalid FDA approval and an unlawful order, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

THIRD CAUSE OF ACTION
FDA VIOLATIONS OF APA, FDCA & PHSA DUE TO FDA IMPROPER APPROVAL OF COMIRNATY VACCINE

118. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

119. The FDA Comirnaty Approval must be found unlawful and set aside due to numerous distinct violations of the Administrative Procedures Act, the FDCA

and PHSA, and the FDA's own rules, regulations, procedures and policies, as well as the requirements set forth in the June 2020 Industry Guidance.

120. FDA's reliance on fundamentally flawed scientific studies, covering participants for months rather than years, in licensing the Comirnaty is a violation of the Administrative Procedure Act insofar its decision is "unsupported by substantial evidence," 5 U.S.C. § 706(2)(E), as well as the FDCA requirements for approvals to be supported by substantial evidence, which includes data from "well controlled" clinical trials. 21 U.S.C. §§ 355(d)-(e). First, the FDA erred in granting approval of Comirnaty without completion of a Phase III clinical trial, required under its own regulations and the June 2020 Industry Guidance. Second, the FDA Comirnaty Approval relied on interim test results for only two months using the full study sample. Pfizer/BioNTech submitted interim results that followed participants for up to six months, but these results are invalid as they are not the result of a "well controlled" clinical trial due to the fact that 93% of participants had been unblinded.

121. The FDA's approval of Comirnaty is also arbitrary and capricious, and unsupported by substantial evidence, insofar as it permitted Pfizer/BioNTech to exclude important "special populations" from clinical trials, in particular: (1) individuals with previous COVID-19 infections; (2) women who are pregnant or nursing, and whose results also apply to women who want to become pregnant and their unborn children or infants; and (3) those with various medical conditions or

history that may be subject to differing or heightened risks than the general population. Despite the fact that the FDA expressly directed vaccine developers to include these groups in the June 2020 Industry Guidance, the FDA not only approved Comirnaty safety or efficacy data for these groups but refused to provide any contraindication or limitations on administering the vaccines to these groups. The FDA's determinations with respect to those with previous infections, and other excluded special populations, are not supported by ***any*** evidence (instead being merely extrapolations or assumptions), much less the "substantial evidence" required by statute. 21 U.S.C. § 355(h). Further, in failing to collect, or require, any evidence for these key populations, the FDA "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) ("*State Farm*").

122. The FDA also violated the APA insofar as it failed to follow procedures required by law, 5 U.S.C. § 706(2)(D), as well as its own policies and guidance, in particular the June 2020 Industry Guidance, and therefore constitutes an unexplained and unannounced departure from previous policy that must be reversed. *See, e.g., Manin v. National Transp. Safety Bd.*, 627 F.3d 1239, 1243 (D.C. Cir. 2011). The FDA skipped altogether key procedural protections such as standard Advisory Committee review process, which entails public notice and comment procedures for

controversial issues. Moreover, as the FDA itself acknowledges, its approval timeline was "unprecedented," because it skipped or waived important procedural requirements, in particular, the completion of well controlled clinical trials covering the "special populations" required in the June 2020 Industry Guidance.

123. As in *Rumsfeld II* regarding mandatory anthrax vaccinations, "[t]his Court has an obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety." *Rumsfeld II*, 341 F.Supp.2d at 19. Unfortunately, the FDA's review and approval of the Comirnaty Vaccine fell woefully short of the substantive and procedural requirement sets forth in the FDCA, the PHSA, the FDA's own rules, regulations and policies, and the Administrative Procedures Act.

124. As a result of Defendant FDA's improper and invalid approval of Comirnaty, Plaintiff service members will be forced to take what amounts to an experimental vaccine, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

FOURTH CAUSE OF ACTION
FDA VIOLATIONS OF ADMINISTRATIVE PROCEDURE ACT DUE TO IMPROPER PURPOSE FOR COMIRNATY APPROVAL

125. Plaintiffs reallege the facts in Paragraphs 1 through 1047 as if fully set forth in this Count.

126. The FDA's approval of the Comirnaty Vaccine violated the substantive provisions of the FDCA and PHSA, and it exceeded its "statutory jurisdiction, authority or limitations," 5 U.S.C. §706(2)(C), insofar as it based its decision on impermissible criteria, namely, the desire to enable federal vaccine mandates for nearly all Americans, rather than on whether Comirnaty is safe and effective under the FDCA and "safe, pure, and potent" under the PHSA. 42 U.S.C. § 262(C)(i)(1).

127. The FDA's actions were also "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 702(2)(A). Basing its approval decision on improper, impermissible, and undisclosed reasons violates the APA's fundamental requirement that agencies decision must be "the product of reasoned decision making." *State Farm*, 463 U.S. at 43. Where, as here, there is significant evidence of improper purposes, and significant departures from normal decision-making processes, this constitutes evidence of "the FDA's bad faith that renders its decision arbitrary and capricious." *Tummino v. Torti*, 603 F.Supp.2d 519, 544 (E.D.N.Y. 2009) ("*Tummino*") (citation omitted).

128. The strongest evidence that FDA's actions were driven by improper considerations—to facilitate vaccine mandates—is the timing. The FDA Comirnaty Approval was announced just over two weeks before the issuance of the Federal Employee and Federal Contractor Mandates, along with the proposed OSHA Mandate affecting 100 million employees. This conclusion is reinforced by

SECDEF's decision to issue the DOD Mandate the very next day. Further evidence of the FDA's improper purpose is its "unprecedented timeline," *see supra* Coleman, note 10, for approval, combined with skipping required procedures and truncating clinical trials needed to demonstrate safety and efficacy studies, despite widespread evidence of rapidly decreasing effectiveness over time.

129. Where an agency's decisions are driven by improper motives or extra-statutory criteria, rather than its scientific expertise, then the courts do not owe the agency deference, or the "presumption of regularity" to which it would otherwise be due. *Citizens to Pres. Overton Park, Inc. v. Volpe,* 401 U.S. 402, 415, 91 S. Ct. 814, 28 L.Ed.2d 136 (1971), *abrogated on other grounds by Califano v. Sanders,* 430 U.S. 99, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). Nor are courts required to bury their head in the sand and "defer" to the agency's pretextual explanations for its actions and decision making. *See, e.g., Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2574-76 204 L.Ed.2d 978 (2019).

FIFTH CAUSE OF ACTION
FDA AND DOD VIOLATIONS OF FDCA AND PHSA TREATING SAME PRODUCT AS EUA AND LICENSED VACCINE AND FINDING THAT THE TWO PRODUCTS ARE INTERCHANGEABLE

130. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

131. FDA violated the substantive terms of the FDCA and PHSA governing

EUA vaccines and licensed vaccines, and exceeds its statutory authority in violation of Section 706(2)(C) of the APA, by unlawfully trying to establish equivalence between what are two legally distinct vaccines subject to distinct, and mutually exclusive approval requirements and regulatory regimes.

132. The same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use under distinct regulatory regimes. Yet that is precisely what the FDA has done by: (1) simultaneously licensing Comirnaty Vaccine and re-issuing the EUA for the BioNTech Vaccine for the same indication (individuals 16 years or older); (2) re-issuing and expanding the existing BioNTech Vaccine EUA for children of 12-15 years of age and permitting the licensed Comirnaty Vaccine to be used for this group; and (3) finding that the EUA BioNTech Vaccine and licensed Comirnaty Vaccine can be used "interchangeably" and may be substituted for each other. *See* Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

133. The FDA exceeds its statutory authority, and abuses its discretion, when it applies two distinct regulatory regimes to the same product. *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020) (holding that the FDA's determination that it could choose to regulate a product as either a drug or a device, or both, as arbitrary and capricious and in excess of statutory authority). This Court must do the same here, vacate the Comirnaty approval, and remand this issue to the

FDA for reconsideration with appropriate guidance.

134. The FDA licensed a product that is not available, and then informed the general public that the EUA-labeled and manufactured product can be used "interchangeably," and can be substituted, for the licensed product. The FDA provides no justification for ignoring and nullifying these express statutory requirements of the FDCA, which also has the intended effect of nullifying Plaintiffs' rights to informed consent and to refuse the administration of an experimental vaccine.

135. The FDA erred, and acted contrary to law and the FDA's own rules and policies, where it found that the licensed Comirnaty Vaccine "can be used interchangeably" with the EUA BioNTech Vaccine. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262, in relation to a "reference product," which is a biological product licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product; in this case, the FDA-licensed Comirnaty Vaccine. But the "interchangeable" product, the EUA BioNTech Vaccine, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k), and there is no indication that any such application was ever filed by BioNTech, much less reviewed or approved by the FDA.

136. The FDA's "interchangeability" determination also reverses the temporal order of the licensed product and the interchangeable product. The licensing of the reference product under 42 U.S.C. § 262(a) is the first licensed product, and therefore the basis for determining the interchangeability of the later product. Here, however, the EUA BioNTech Vaccine is the earlier product that was not manufactured in a BLA-compliant manner by the FDA's own admission. Thus, the "interchangeability" determination appears to be a transparent attempt to ***retroactively license*** non-BLA compliant lots of BioNTech Vaccine, solely for the purpose of enabling the vaccine mandate.

137. The FDA simply has not explained what "interchangeable" means in this context, nor could it because its use of these terms is incompatible with the PHSA's statutory framework. Accordingly, this Court must remand the matter to the FDA to explain its decisions. *See, e.g., A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (remanding to the FDA to explain what "bioequivalency" means in the animal drug context and how the evidence relied on by the FDA satisfied the standard).

138. The DOD and the Armed Services are similarly violating these statutes insofar as they mandate, or permit pursuant to the mandate, providers to administer the BioNTech Vaccine "as if" it were the licensed Comirnaty Vaccine, based on the FDA's foregoing statutory violations and willful statutory misinterpretations.

139. Plaintiffs are harmed by Defendants' unlawful actions which are an improper maneuver conducted to override federal statutory rights to informed medical consent, to coerce and deceive service members (and the 100 million other Americans subject to these mandates) into believing that they can be forced to take an experimental vaccine that they have statutory and constitutional rights to refuse.

SIXTH CAUSE OF ACTION
VIOLATIONS OF ADMINISTRATIVE PROCEDURE ACT
DUTY TO INSTITUTE NOTICE AND COMMENT RULEMAKING

140. Plaintiffs reallege the facts in Paragraphs 1 through 104 as if fully set forth in this Count.

141. The FDA's decision to grant the Comirnaty Vaccine BLA was driven by improper and extra-statutory considerations, namely, to enable the imposition of vaccine mandates. The FDA sought to avoid its obligations under the Federal Advisory Committee Act and the Administrative Procedures Act—disingenuously claiming that the Comirnaty Vaccine BLA did not raise any "controversial" issues that would have benefitted from the Advisory Committee process—to provide public notice and opportunity for comment on its decisions, and to engage in reasoned decision making, rather than engaging in politically motivated subterfuge.

142. Defendant FDA was required to provide an opportunity for public review of the data and the FDA's policy arguments supporting its decision to grant the BLA through the Advisory Committee, and the consequent opportunity for

public notice and comment. The FDA and other agencies like the DOD should be required to institute a notice and comment rulemaking proceeding to address the implications of federal vaccine mandates.

143. In addition, this court should direct the FDA and DOD to institute public notice-and-comment rulemaking proceedings to address both the scientific evidence regarding the safety and efficacy of the COVID-19 vaccines, alternatives to vaccination or vaccine mandates, the legal basis for a vaccine mandate, whether vaccine mandates can be crafted in a manner that satisfies the requirements of strict scrutiny, and the proportionality of proposed conditions and sanctions for refusal.

SEVENTH CAUSE OF ACTION
VIOLATION OF THE SUBSTANTIVE RIGHT TO DUE PROCESS TO REFUSE UNWANTED, UNNECESSARY AND UNPROVEN MEDICAL TREATMENT

144. Plaintiffs reallege the facts in Paragraphs 1 through 104 as if fully set forth in this Count.

145. The DOD Mandate requires Plaintiffs to take a vaccine without their consent—and against the expert medical advice of their immunologist—thereby depriving them of their right to refuse unwanted, unnecessary, and unproven experimental medical treatments.

146. The Supreme Court has recognized that the Fifth, Ninth and Fourteenth Amendments protect an individual's right to privacy. The Constitution protects a

person's right to "refus[e] unwanted medical care." *Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261,278 (1990); *see also King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same). The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v.Quill*, 521 U.S. 793, 807 (1997).

147. The Supreme Court has, however, cautioned lower courts to "exercise the utmost care" in "extending constitutional protection to an asserted right or liberty interest." *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997). Recent decisions by lower courts addressing mandates have erroneously described the substantive due process right asserted by Plaintiffs as a "right to refuse vaccines." *Klaassen*, 2021 WL 3073926, at *24.

148. Plaintiffs here do not assert a generic right to refuse a vaccination. Instead, they assert a right to refuse mandatory medical treatment that is (1) still experimental and whose long-term efficacy is "not proven," *Klaassen*, 2021 WL 3073926, at *17, (2) that is unnecessary, based on long-standing scientific evidence of natural immunity from previous infection, and (3) has not been shown to have any therapeutic effect. Plaintiffs' substantive due process claims should instead be analyzed as part of the long line of cases that recognize a fundamental right against involuntarily participation in medical experiments, which in most cases were

conducted by Defendant DOD. *See, e.g., Heinrich v. Sweet,* 62 F.Supp.2d. 282 (D.Mass.1999); *Stadt v. Univ. of Rochester,* 921 F.Supp. 1023 (W.D.N.Y.1996); *In re Cincinnati Radiation Litig.,* 874 F.Supp. 796 (S.D.Ohio 1995); *United States v. Stanley,* 483 U.S. 669, 107 S.Ct. 3054, 97 L.Ed.2d 550 (1987)

149. This vaccine was deemed experimental until last month, and has only existed for a little over a year. The vaccine uses an entirely novel mRNA technology and delivery system. The FDA's rushed, politicized, and unlawful approval process does not change its experimental status. The FDA's actions in simultaneously maintaining the EUA for BioNTech Vaccine and licensing Comirnaty for the same indication (individuals 16 years or older), demonstrate that this product is ***still experimental***, and the FDA and Armed Services Guidance statements that the two are "interchangeable" ensures that service members will be administered an experimental EUA-labeled and manufactured products pursuant to the DOD Mandate.

150. This conclusion is further reinforced by the recent debate over booster shots, which demonstrates that there is no scientific consensus on Comirnaty's efficacy, or even the proper dosage. "As COVID-19 is a new disease, and the vaccines are even newer, the long-term efficacy of immunity derived from vaccination and infection is not proven." *Klaassen*, 2021 WL 3073926, at *12. The Pfizer Factsheet admits that Comirnaty's "duration of protection against COVID-19

is currently unknown."[71]

151. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Rumsfeld I*, 297 F.Supp.2d at 135. Further, because COVID-19 presents a minimal risk of hospitalization or death for service members like Plaintiffs, particularly those with natural immunity from previous infections, and because the FDA did not consider any clinical trial data on safety or efficacy for special populations like Plaintiffs with previous infections or for pregnant or nursing women, the FDA has failed to demonstrate any benefit for these special populations. As such, the DOD Mandate is closer to the *Heinrich, Stadt*, and *Cincinnati* cases that involved medical experiments whose therapeutic value was unknown. *See e.g.*, *Amend v. Bioport, Inc.*, 322 F.Supp.2d 848, 871 (W.D. Mich. 2004) (discussing substantive due process rights against involuntary participation in medical experiments).

152. Defendants cannot show that they have a compelling interest in coercing Plaintiffs into taking a COVID-19 vaccine, because the DOD has no compelling interest in treating employees with natural immunity any differently from employees who obtained immunity from a vaccine. Substantial research establishes

[71] FDA, *Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty* at 4 (Sept. 22, 2021), available at: https://www.fda.gov/media/144414/download (last visited Sept. 29, 2021).

that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. *See supra* Section VI.D. Further, the rapidly declining efficacy against re-infection (e.g., 40% after six months) casts doubt on anyclaim that the vaccine prevents spread of the virus, and thereby the public health justification on which the mandate is premised.

153. Plaintiffs will suffer damage from Defendants' conduct because they must either accept unwanted, unnecessary, and unproven medical treatment, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

EIGHTH CAUSE OF ACTION
DOD IMPOSITION OF UNCONSTITUTIONAL CONDITIONS

154. Plaintiffs reallege the facts in Paragraphs 1 through 104 as if fully set forth in this Count.

155. The Due Process Clause of the Fourteenth Amendment provides: "nor shall any state deprive any person of life, liberty, or property, without due process of law … ." U.S. CONST. AMEND. XIV, sec. 1.

156. The DOD Vaccine Mandate imposes unconstitutional conditions on Plaintiffs by requiring them to accept unwanted, unnecessary, and unproven experimental vaccine, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and

fundamental rights. *See, e.g.*, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them").

157. The unconstitutional conditions doctrine and due process rights combine to invalidate the DOD Vaccine Mandate as applied to Plaintiffs. That result occurs because the DOD has not and cannot show that forcing Plaintiffs to take the vaccine reduces any risk that they will become infected with and spread the virus to other DOD personnel or their communities.

158. Accordingly, the DOD Vaccine Mandate contravenes the Due Process Clause and imposes unconstitutional conditions.

NINTH CAUSE OF ACTION
VIOLATION OF THE EQUAL PROTECTION CLAUSE OF THE FIFTH AND FOURTEENTH AMENDMENTS

159. Plaintiffs reallege the facts in Paragraphs 1 through 104 as if fully set forth in this Count.

160. The DOD Mandate and related mandates violate the Equal Protection Clause under the Fifth and Fourteenth Amendments of the United States Constitution.

161. In addition to the DOD Mandate, there have been announced multiple, unprecedented federal mandates requiring U.S. citizens to be vaccinated against

COVID-19, upon pain of losing their jobs or their livelihood. At the same time, the Executive has disclaimed any COVID-19 vaccination requirement for illegal aliens, (many of whom refuse vaccination), even if they are being released into the U.S., rather than being immediately deported. Consequently, unauthorized aliens will not be subject to any vaccination requirements, even when released directly into the United States (where most will remain), while at least 100 million U.S. citizens will be subject to unprecedented vaccination mandates.

162. This discrimination in favor of unauthorized aliens violates the Equal Protection Clause. Alienage is a suspect class that triggers strict scrutiny. More typically (and almost invariably previously), this discrimination was *against* aliens rather than for them. *See*, *e.g.*, *Graham v. Richardson*, 403 U.S. 365, 371, 375-376 (1971); *Application of Griffiths*, 413 U.S. 717, 721 (1973). But the same principle applies to favoritism *against* U.S. citizens in favor of aliens. Defendants' actions could never conceivably pass strict scrutiny.

163. The DOD Mandate also singles out, and discriminates against, Plaintiffs based on their medical history, disabilities and/or medical conditions. There is similarly no rational basis for such differential treatment that reduces patriotic service members to the status of second-class citizens in the nation they are sworn to defend and have served loyally.

164. Plaintiffs will be harmed due to Defendants' unlawful and

unconstitutional vaccination mandates that would deprive them of their livelihoods, liberty, property rights, and fundamental constitutional rights under the U.S. Constitution, simply for asserting their statutory and constitutional rights, while refusing to impose similar obligations on similarly situated persons solely on the basis of alienage/national origin, medical history/conditions and/or disabilities.

TENTH CAUSE OF ACTION
CIVIL RIGHTS VIOLATIONS OF 42 U.S.C. § 1983

165. Plaintiffs reallege the facts in Paragraphs 1 through **Error! Reference source not found.** as if fully set forth in this Count.

166. 42 U.S.C. § 1983 provides a civil right of action for deprivations of constitutional protections taken under color of law. Plaintiffs have alleged violations of the rights to Substantive Due Process (Seventh Cause of Action), their rights against the imposition of unconstitutional conditions (Eighth Cause of Action), and right to Equal Protection (Ninth Cause of Action).

167. Plaintiffs are entitled to declaratory and injunctive relief pursuant to 42 U.S.C. § 1983 because they are being deprived of "rights, privileges, or immunities secured by the Constitution and laws." Section 1983 thus supports both Plaintiff's constitutional and statutory causes of action against DOD, FDA and HHS Defendants because Section 1983 protects rights "secured by the Constitution and laws." 42 U.S.C. § 1983.

ELEVENTH CAUSE OF ACTION
VIOLATION OF SEPARATION OF POWERS AND FEDERALISM

168. Plaintiffs reallege the facts in Paragraphs 1 through 104 as if fully set forth in this Count.

169. The DOD Mandate and the FDA Comirnaty Approval must be considered as part of a larger effort to impose unconstitutional vaccine mandates on nearly every U.S. citizen or legal resident. The unprecedented federal vaccine mandates have been or will be enacted solely through administrative action, without authorization from Congress and over the strong objections from dozens of State governors.

170. The DOD Mandate and other federal mandates, imposed through administrative fiat, are in many ways similar to the CDC's eviction moratorium that the Supreme Court recently struck down as exceeding the authority granted to the CDC by enabling statute. Where, as in the CDC eviction moratorium and the proposed OSHA Mandate, "an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the economy," the Court must "greet its announcement with a measure of skepticism." *See generally Alabama Realtors I*, 2021 WL 1779282, *8. Further, Congress must "speak clearly when authorizing an agency to exercise vast powers of economic and political significance." *Id.*, 2021 WL 3783142, at *3 (internal citation and quotation omitted).

171. Congress has not enacted any legislation authorizing the DOD Mandate, or granted any agency the authority to enact a federal mandate, nor is there any indication that it intends to do so. This Court must therefore reject the efforts of Defendants to bypass Congress, the States, and the Constitution, to enact by administrative fiat an unconstitutional vaccine mandate.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully ask this Court to:

A. Issue a declaratory judgment that the DOD Mandate is unlawful and in violation of AR 40-562 and federal laws governing informed consent.

B. Enjoin any implementation of the DOD Mandate by the Armed Services or other DOD components, and to stay the effective date thereof.

C. Declare unlawful, vacate and remand the FDA Comirnaty Approval to the FDA for reconsideration consistent with appliable laws and regulations, and any additional guidance this Court may provide, and stay the effective date thereof.

D. Issue a declaratory judgment that the FDA may not simultaneously treat the same product as an EUA product and licensed product for the same indication and use, and that the licensed Comirnaty Vaccine and the EUA BioNTech Vaccine can be used "interchangeably" or "substituted" for each other is unlawful.

E. Find that all Plaintiffs with natural immunity due to previous infection are entitled to a medical exemptionfrom COVID-19 vaccination under AR 40-562.

F. Declare unlawful and enjoin the DOD and the Armed Services from treating the EUA BioNTech Vaccine "as if" it were the licensed Comirnaty Vaccine, and from administering any EUA vaccine pursuant to the DOD Mandate.

G. Issue a declaratory judgment that the DOD Mandate infringes upon Plaintiffs' constitutional right to refuse unwanted, unnecessary, and unproven medical treatment, imposes unconstitutional conditions and violates equal protection.

H. Direct the FDA to institute notice-and-comment rulemaking to consider the legal and constitutional issues raised by federal vaccine mandates.

I. Award any other relief this Court may deem just and proper, including but not limited to an award of plaintiffs' costs and attorneys' fees and any other relief this Court may find appropriate.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Complaint for Declaratory Judgment, Stay, Temporary Restraining Order and Permanent Injunctive Relief and Memorandum in Support Thereof using the CM/ECF system, and that I have delivered the filing to the Defendants by FedEx at the following addresses:

This 6th day of October, 2021.

Respectfully Submitted,

/s/ Ibrahim Reyes
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United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
November 12, 2021
Lyle W. Cayce
Clerk

No. 21-60845

BST Holdings, L.L.C.; RV Trosclair, L.L.C.; Trosclair Airline, L.L.C.; Trosclair Almonaster, L.L.C.; Trosclair and Sons, L.L.C.; Trosclair ; Trosclair, Incorporated; Trosclair Carrollton, L.L.C.; Trosclair Claiborne, L.L.C.; Trosclair Donaldsonville, L.L.C.; Trosclair Houma, L.L.C.; Trosclair Judge Perez, L.L.C.; Trosclair Lake Forest, L.L.C.; Trosclair Morrison, L.L.C.; Trosclair Paris, L.L.C.; Trosclair Terry, L.L.C.; Trosclair Williams, L.L.C.; Ryan Dailey; Jasand Gamble; Christopher L. Jones; David John Loschen; Samuel Albert Reyna; Kip Stovall; Answers in Genesis, Incorporated; American Family Association, Incorporated; Burnett Specialists; Choice Staffing, L.L.C.; Staff Force, Incorporated; Leadingedge Personnel, Limited; State of Texas; HT Staffing, Limited; doing business as HT Group; The State of Louisiana; Cox Operating, L.L.C.; Dis-Tran Steel, L.L.C.; Dis-Tran Packaged Substations, L.L.C.; Beta Engineering, L.L.C. Optimal Field Services, L.L.C.; The State of Mississippi; Gulf Coast Restaurant Group, Incorporated; The State of South Carolina; The State of Utah; Word of God Fellowship, Incorporated, doing busines as Daystar Television Network,

Petitioners,

versus

Occupational Safety and Health Administration, United States Department of Labor; United States

DEPARTMENT OF LABOR; MARTIN J. WALSH, SECRETARY, U.S. DEPARTMENT OF LABOR; DOUGLAS PARKER, IN HIS OFFICIAL CAPACITY AS ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH,

Respondents.

Petition for Review of
Occupational Safety and Health Administration
Emergency Temporary Standard

Before JONES, DUNCAN, and ENGELHARDT, *Circuit Judges*.

KURT D. ENGELHARDT, *Circuit Judge*:

The Occupational Safety and Health Administration (OSHA) "reasonably determined" in June 2020 that an emergency temporary standard (ETS) was "not necessary" to "protect working people from occupational exposure to infectious disease, including COVID-19." *In re AFL-CIO*, 2020 WL 3125324, at *1 (D.C. Cir. June 11, 2020). This was not the first time OSHA had done this; it has refused several times to issue ETSs despite legal action urging it do so. *See, e.g.*, *In re Int'l Chem. Workers Union*, 830 F.2d 369 (D.C. Cir. 1987) (per curiam). In fact, in its fifty-year history, OSHA has issued just ten ETSs.[1] Six were challenged in court; only one survived.[2] The reason for the rarity of this form of emergency action is

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[1] CONG. RSCH. SERV., OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA): EMERGENCY TEMPORARY STANDARDS (ETS) AND COVID-19, at 34 tbl. A-1 (Nov. 10, 2021), *available at* https://crsreports.congress.gov/product/pdf/R/R46288.

[2] It bears noting at the outset that most of the few ETSs issued by OSHA were immediately stayed pending merits review. *See Asbestos Info. Ass'n/N. Am. v. OSHA*, 727 F.2d 415, 418 (5th Cir. 1984); *Indus. Union Dep't, AFL-CIO v. Bingham*, 570 F.2d 965, 968 (D.C. Cir. 1977); *Taylor Diving Salvage Co. v. U.S. Dep't of Lab.*, 537 F.2d 819, 820–21 (5th

simple: courts and the Agency have agreed for generations that "[e]xtraordinary power is delivered to [OSHA] under the emergency provisions of the Occupational Safety and Health Act," so "[t]hat power should be delicately exercised, and only in those emergency situations which require it." *Fla. Peach Growers Ass'n v. U.S. Dep't of Lab.*, 489 F.2d 120, 129–30 (5th Cir. 1974).

This case concerns OSHA's most recent ETS—the Agency's November 5, 2021 Emergency Temporary Standard (the "Mandate") requiring employees of covered employers to undergo COVID-19 vaccination or take weekly COVID-19 tests and wear a mask.[3] An array of petitioners seeks a stay barring OSHA from enforcing the Mandate during the pendency of judicial review. On November 6, 2021, we agreed to stay the Mandate pending briefing and expedited judicial review. Having conducted that expedited review, we reaffirm our initial stay.

I.

OSHA promulgated its much anticipated[4] vaccine mandate on November 5, 2021. Framed as an ETS, the Mandate requires all employers of 100 or more employees to "develop, implement, and enforce a mandatory COVID-19 vaccination policy" and require any workers who remain

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Cir. 1976) (per curiam); *Fla. Peach Growers Ass'n v. U.S. Dep't of Lab.*, 489 F.2d 120, 126 (5th Cir. 1974).

[3] *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928).

[4] Debates over the Biden Administration's forthcoming vaccine mandate roiled the country throughout much of the Fall. For obvious reasons, the Mandate affects every person in America in one way or another.

unvaccinated to "undergo [weekly] COVID-19 testing and wear a face covering at work in lieu of vaccination." 86 Fed. Reg. 61,402, 61,402.

On the afternoon of the Mandate's publication, a diverse group of petitioners (including covered employers, States, religious groups, and individual citizens) moved to stay and permanently enjoin the mandate in federal courts of appeals across the nation. Finding "cause to believe there are grave statutory and constitutional issues with the Mandate," we intervened and imposed a temporary stay on OSHA's enforcement of the Mandate. For ease of judicial review, and in light of the pressing need to act immediately, we consolidated our court's petitions under the case number captioned above.

Many of the petitioners are covered private employers within the geographical boundaries of this circuit.[5] Their standing[6] to sue is obvious—the Mandate imposes a financial burden upon them by deputizing their participation in OSHA's regulatory scheme, exposes them to severe financial risk if they refuse or fail to comply, and threatens to decimate their workforces (and business prospects) by forcing unwilling employees to take their shots, take their tests, or hit the road.

[5] Because these petitioners are the targets of the Mandate and bear the brunt of OSHA's regulatory power, we principally analyze the petitions from their perspective. This is not to say that the claims of other petitioners such as States or individual citizens would be any less successful on a thorough analysis.

[6] "Only one of the petitioners needs to have standing to permit us to consider the petition for review." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

The petitioners seek a stay—and ultimately a permanent injunction—of the Mandate's enforcement pending full judicial review of the Mandate. We address their request for a stay today.[7]

II.

The "traditional stay factors . . . govern a request for a stay pending judicial review." *Nken v. Holder*, 556 U.S. 418, 426 (2009). Under the traditional stay standard, a court considers four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).

Each of these factors favors a stay here.

A.

We first consider whether the petitioners' challenges to the Mandate are likely to succeed on the merits. For a multitude of reasons, they are.

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[7] Our November 6, 2021 stay order preserved the status quo during the pendency of briefing. The unusual procedural posture of this case makes for an unusual process. Ordinarily, a federal plaintiff aggrieved by an adversary's threatened course of action must go to a *district court* to seek injunctive relief at the outset. In this ordinary scenario, a preliminary injunction precedes a permanent injunction, and trial-court review precedes appellate review. But this is not a typical case. Here, the statute giving OSHA the power to issue emergency temporary standards like the Mandate also provides for direct and immediate judicial review in "the United States court of appeals for the circuit wherein" "[a]ny person who may be adversely affected by" an ETS "resides or has his principal place of business." *See* 29 U.S.C. § 655(f). Satisfied of our jurisdiction to proceed under that provision, but mindful of our unusual procedural posture, we apply the traditional factors for a stay pending judicial review and draw factual support from the attachments to the pleadings, uncontested facts, and judicial notice.

We begin by stating the obvious. The Occupational Safety and Health Act, which created OSHA, was enacted by Congress to assure Americans "safe and healthful working conditions and to preserve our human resources." *See* 29 U.S.C. § 651 (statement of findings and declaration of purpose and policy). It was not—and likely *could* not be, under the Commerce Clause and nondelegation doctrine[8]—intended to authorize a workplace safety administration in the deep recesses of the federal bureaucracy to make sweeping pronouncements on matters of public health affecting every member of society in the profoundest of ways. *Cf. Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2488–90 (2021) (per curiam).

On the dubious assumption that the Mandate *does* pass constitutional muster—which we need not decide today[9]—it is nonetheless fatally flawed on its own terms. Indeed, the Mandate's strained prescriptions combine to make it the rare government pronouncement that is both overinclusive (applying to employers and employees in virtually all industries and workplaces in America, with little attempt to account for the obvious differences between the risks facing, say, a security guard on a lonely night shift, and a meatpacker working shoulder to shoulder in a cramped warehouse) *and* underinclusive (purporting to save employees with 99 or more coworkers from a "grave danger" in the workplace, while making no attempt to shield employees with 98 or fewer coworkers from the very same

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[8] The nondelegation doctrine constrains Congress's ability to delegate its legislative authority to executive agencies. *See, e.g.*, *Mistretta v. United States*, 488 U.S. 361, 371–72 (1989) ("The Constitution provides that '[a]ll legislative Powers herein granted shall be vested in a Congress of the United States' . . . and we have long insisted that 'the integrity and maintenance of the system of government ordered by the Constitution' mandate that Congress generally cannot delegate its legislative power to another Branch." (first quoting U.S. CONST. art. I, § 1; then quoting *Field v. Clark*, 143 U.S. 649, 692 (1892))).

[9] *But see infra* subsection II.A.2.f.

threat). The Mandate's stated impetus—a purported "emergency" that the entire globe has now endured for nearly two years,[10] and which OSHA itself spent nearly two *months* responding to[11]—is unavailing as well. And its promulgation grossly exceeds OSHA's statutory authority.

1.

After the President voiced his displeasure with the country's vaccination rate in September,[12] the Administration pored over the U.S. Code in search of authority, or a "work-around,"[13] for imposing a national

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[10] As Justice Gorsuch recently observed, society's interest in slowing the spread of COVID-19 "cannot qualify as [compelling] forever," for "[i]f human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency." *Does 1–3 v. Mills*, --- S. Ct. ---, 2021 WL 5027177, at *3 (Oct. 29, 2021) (Gorsuch, J., dissenting); *see also Fla. Peach Growers*, 489 F.2d at 131 (situation ongoing for "last several years . . . fail[ed] to qualify for [OSHA] emergency measures").

[11] The President announced his intention to impose a national vaccine mandate on September 9, 2021. *See, e.g.*, Kevin Liptak & Kaitlan Collins, *Biden Announces New Vaccine Mandates that Could Cover 100 Million Americans*, CNN (Sept. 9, 2021), https://www.cnn.com/2021/09/09/politics/joe-biden-covid-speech/index.html ("'We've been patient, but our patience is wearing thin, and your refusal has cost all of us,' Biden said, his tone hardening toward Americans who still refuse to receive a vaccine despite ample evidence of their safety and full approval of one . . . ."). OSHA issued the Mandate nearly two months later, on November 5, 2021, and the Mandate itself prominently features yet another two-month delay. One could query how an "emergency" could prompt such a "deliberate" response. In similar cases, we've held that OSHA's failure to act promptly "does not conclusively establish that a situation is not an emergency," but "may be evidence that a situation is not a *true* emergency." *Asbestos Info.*, 727 F.2d at 423 (emphasis added).

[12] *See supra* note 11.

[13] On September 9, 2021, White House Chief of Staff Ron Klain retweeted MSNBC anchor Stephanie Ruhle's tweet that stated, "OSHA doing this vaxx mandate as an emergency workplace safety rule *is the ultimate work-around for the Federal govt to require vaccinations.*" *See, e.g.*, Pet'rs Burnett Specialists, Choice Staffing, LLC, and Staff Force Inc.'s Reply Brief at 4 (emphasis added).

vaccine mandate. The vehicle it landed on was an OSHA ETS. The statute empowering OSHA allows OSHA to bypass typical notice-and-comment proceedings for six months by providing "for an emergency temporary standard to take immediate effect upon publication in the Federal Register" if it "determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." 29 U.S.C. § 655(c)(1).

As the name suggests, *emergency* temporary standards "are an 'unusual response' to 'exceptional circumstances.'" *Int'l Chem. Workers*, 830 F.2d at 371 (quoting *Pub. Citizen Health Rsch. Grp. v. Auchter*, 702 F.2d 1150, 1155 (D.C. Cir. 1983)). Thus, courts have uniformly observed that OSHA's authority to establish emergency temporary standards under § 655(c) "is an 'extraordinary power' that is to be 'delicately exercised' in only certain 'limited situations.'" *Id.* at 370 (quoting *Pub. Citizen*, 702 F.2d at 1155).[14]

But the Mandate at issue here is anything *but* a "delicate[] exercise[]" of this "extraordinary power." *Cf. Pub. Citizen*, 702 F.2d at 1155. Quite the opposite, rather than a delicately handled scalpel, the Mandate is a one-size-fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly "grave danger" the Mandate purports to address.

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[14] The Agency has thus conceded in the past that "[t]he OSH Act does not authorize OSHA to issue sweeping health standards to address entire classes of known and unknown infectious diseases on an emergency basis without notice and comment." *See* Department of Labor's Resp. to the Emergency Pet. for a Writ of Mandamus at 33–34, *In re AFL-CIO*, No. 20-1158 (D.C. Cir. May 29, 2020) [hereinafter OSHA D.C. Circuit Brief].

2.

Thus, as § 655(c)(1) plainly provides, to be lawfully enacted, an ETS must: (1) address "substances or agents determined to be toxic or physically harmful"—or "new hazards"—in the workplace; (2) show that workers are exposed to such "substances," "agents," or "new hazards" in the workplace; (3) show that said exposure places workers in "grave danger"; and (4) be "necessary" to alleviate employees' exposure to gravely dangerous hazards in the workplace. As we have noted in the past, the precision of this standard makes it a difficult one to meet. *See Fla. Peach Growers*, 489 F.2d at 130 (observing that OSHA's ETS authority "requires determination of danger from exposure to harmful substances, not just a danger of exposure; and, not exposure to just a danger, but to a grave danger; and, not the necessity of just a temporary standard, but that an emergency [temporary] standard is necessary").[15]

(a)

In its brief, Texas makes a compelling argument that § 655(c)(1)'s neighboring phrases "substances or agents" and "toxic or physically harmful" place an airborne virus beyond the purview of an OSHA ETS in the first place. To avoid "giving unintended breadth to the Acts of Congress," courts "rely on the principle of *noscitur a sociis*—a word is known by the company it keeps." *Yates v. United States*, 574 U.S. 528, 543 (2015) (cleaned up). Here, OSHA's attempt to shoehorn an airborne virus that is both widely present in society (and thus not particular to any workplace) and non-life-

[15] In prior litigation, OSHA acknowledged that many "workplaces" covered by a COVID-19 ETS "are not merely workplaces," but are also "stores, restaurants, and other places occupied by workers and the general public alike, in which the measures called for require a broader lens—and at times a broader mandate—than available to OSHA." *See* OSHA D.C. Circuit Brief at 20.

threatening to a vast majority of employees into a neighboring phrase connoting *toxicity* and *poisonousness* is yet another transparent stretch. Other cases involving OSHA (though not ETSs per se) shed further light on the intended meaning of these terms. *See, e.g.*, *UAW v. OSHA*, 938 F.2d 1310, 1314 (D.C. Cir. 1991). *See generally Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607 (1980). Any argument OSHA may make that COVID-19 is a "new hazard[]" would directly contradict OSHA's prior representation to the D.C. Circuit that "[t]here can be no dispute that COVID-19 is a *recognized* hazard." *See* OSHA D.C. Circuit Brief at 25 (emphasis added).

(b)

A natural first step in enacting a lawful ETS is to show that employees covered by the ETS are in fact *exposed* to the dangerous substances, agents, or hazards at issue—here, COVID-19. *See, e.g.*, *Int'l Chem. Workers*, 830 F.2d at 371 (noting OSHA's stated view "that a finding of 'grave danger' to support an ETS be based upon exposure in actual levels found in the workplace"). As it pertains to the vast majority of private employees covered by the Mandate, however, OSHA fails to meet this threshold burden. In defending the Mandate before this court, the Government credits OSHA with "describ[ing] myriad studies showing workplace [COVID-19] 'clusters' and 'outbreaks' and other significant 'evidence of workplace transmission' and 'exposure.'" *See* Resp'ts' Opp'n to Emergency Stay Mot. at 8. But this misses the mark, as OSHA is required to make findings of exposure—or at least the presence of COVID-19—in *all* covered workplaces.

Of course, OSHA cannot possibly show that every workplace covered by the Mandate currently has COVID-positive employees, or that every industry covered by the Mandate has had or will have "outbreaks." As

discussed below, this kind of overbreadth plagues the Mandate generally. *See infra* subsection II.A.2.d.

(c)

Equally problematic, however, is that it remains unclear that COVID-19—however tragic and devastating the pandemic has been—poses the kind of grave danger § 655(c)(1) contemplates. *See, e.g.*, *Int'l Chem. Workers*, 830 F.2d at 371 (noting that OSHA itself once concluded "that to be a 'grave danger,' it is not sufficient that a chemical, such as cadmium, can cause *cancer* or *kidney damage* at a high level of exposure" (emphasis added)). For starters, the Mandate itself concedes that the effects of COVID-19 may range from "mild" to "critical." As important, however, the status of the spread of the virus has varied since the President announced the general parameters of the Mandate in September. (And of course, this all assumes that COVID-19 poses any significant danger to workers to begin with; for the more than *seventy-eight* percent[16] of Americans aged 12 and older either fully or partially inoculated against it, the virus poses—the Administration assures us—little risk at all.) *See, e.g.*, 86 Fed. Reg. 61,402, 61,402–03 ("COVID-19 vaccines authorized or approved by the [FDA] effectively protect vaccinated individuals against severe illness and death from COVID-19.").

The Administration's prior statements in this regard further belie the notion that COVID-19 poses the kind of emergency that allows OSHA to take the extreme measure of an ETS. In reviewing agency pronouncements, courts need not turn a blind eye to the statements of those issuing such pronouncements. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). In fact, courts have an affirmative duty *not* to do so. It is thus

[16] *See* CDC, COVID DATA TRACKER, https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

critical to note that the Mandate makes no serious attempt to explain why OSHA and the President himself[17] were against vaccine mandates before they were for one here. *See, e.g.*, Occupational Exposure to Bloodborne Pathogens, 54 Fed. Reg. 23,042, 23,045 (May 30, 1989) ("Health in general is an intensely personal matter. . . . OSHA prefers to encourage rather than try to force by governmental coercion, employee cooperation in [a] vaccination program."); Letter from Loren Sweatt, Principal Deputy Assistant Sec'y, OSHA, to Richard L. Trumka, President, AFL-CIO at 3 (May 29, 2020) [hereinafter Sweatt Letter] (acknowledging as a general matter that it "would not be necessary for OSHA to issue an ETS to protect workers from infectious diseases" because "OSHA lacks evidence to conclude that all infectious diseases to which employees may be exposed at a workplace constitute a 'grave danger' for which an ETS is an appropriate remedy"). Because it is generally "arbitrary or capricious" to "depart from a prior policy *sub silentio*," agencies must typically provide a "detailed explanation" for contradicting a prior policy, particularly when the "prior policy has engendered serious reliance interests." *FCC v. Fox*, 556 U.S. at 515. OSHA's reversal here strains credulity, as does its pretextual basis.[18] Such shortcomings are all hallmarks of unlawful agency actions.

To be sure, "OSHA's assessment of . . . scientifically complex [facts] and its balancing of the competing policies that underlie the decision whether to issue an ETS . . . are entitled to great deference," but this is not a case

[17] In December of 2020, the President was quoted as saying, "No I don't think [vaccines] should be mandatory." *See, e.g.*, Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020*, NEWSWEEK (Sept. 10, 2021), https://www.newsweek.com/fact-check-joe-biden-no-vaccines-mandatory-december-2020-1627774.

[18] *See supra* note 13 (Klain endorsement of the term "work-around").

where any amount of deference would make a bit of difference. *Int'l Chem. Workers*, 830 F.2d at 371.

(d)

We next consider the necessity of the Mandate. The Mandate is staggeringly overbroad. Applying to 2 out of 3 private-sector employees in America, in workplaces as diverse as the country itself, the Mandate fails to consider what is perhaps the most salient fact of all: the ongoing threat of COVID-19 is more dangerous to *some* employees than to *other* employees. All else equal, a 28 year-old trucker spending the bulk of his workday in the solitude of his cab is simply less vulnerable to COVID-19 than a 62 year-old prison janitor. Likewise, a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus. The list goes on, but one constant remains—the Mandate fails almost completely to address, or even respond to, much of this reality and common sense.

Moreover, earlier in the pandemic, the Agency recognized the practical impossibility of tailoring an effective ETS in response to COVID-19. *See* OSHA D.C. Circuit Brief at 16, 17, 21, 26 ("Based on substantial evidence, OSHA determined that an ETS is not necessary both because there are existing OSHA and non-OSHA standards that address COVID-19 and because an ETS would actually be counterproductive. . . . To address all employers and to do so with the requisite dispatch, an ETS would at best be an enshrinement of these general and universally known measures that are already enforceable through existing OSHA tools that require employers to assess and address extant hazards. OSHA's time and resources are better spent issuing industry-specific guidance that adds real substance and permits flexibility as we learn more about this virus. Given that we learn more about COVID-19 every day, setting rules in stone through an ETS (and later a

permanent rule) may undermine worker protection by permanently mandating precautions that later prove to be inefficacious. . . . [A]n ETS could only enshrine broad legal standards that are already in place or direct employers to develop COVID-19 response plans specific to their businesses, something employers are already doing. Such a step would be superfluous at best and could be counterproductive to ongoing state, local, and private efforts. . . . Additionally, employers may choose any effective method to abate a recognized hazard under the general duty clause. Contrary to AFL-CIO's argument, this flexibility is likely to improve worker safety, because employers must choose a means of abatement that eliminates the hazard or materially reduces it to the extent feasible."). OSHA itself admitted that "an ETS once issued could very well become ineffective or counterproductive, as it may be informed by incomplete or ultimately inaccurate information." *Id.* at 30, 32–33 (acknowledging further that "[a]dequate safeguards for workers could differ substantially based on geographic location, as the pandemic has had dramatically different impacts on different parts of the country. State and local requirements and guidance on COVID-19 are thus critical to employers in determining how to best protect workers, and OSHA must retain flexibility to adapt its advice regarding incorporation of such local guidance, where appropriate. . . . [A]n ETS meant to broadly cover all workers with potential exposure to COVID-19—effectively *all* workers across the country—would have to be written at such a general level that it would risk providing very little assistance at all").

In light of this immense complexity, one might naturally ask the Agency—is this situation truly amenable to a one-size-fits-all Mandate? The likely answer may be why OSHA has in the past "determined that the best approach for responding to the pandemic is to enforce the existing OSH Act requirements that address infectious disease hazards, while also issuing detailed, industry-specific guidance," which is generally "more effective

than promulgating a rigid set of requirements for all employers in all industries based on limited information." *See* Sweatt Letter at 2. In sum, as OSHA itself has previously acknowledged, an ETS appears to be a "poorly-suited approach for protecting workers against [COVID-19] because no standard that covers all of the Nation's workers would protect all those workers equally." *See id.* at 9.

At the same time, the Mandate is also *underinclusive*. The most vulnerable worker in America draws no protection from the Mandate if his company employs 99 workers or fewer. The reason why? Because, as even OSHA admits, companies of 100 or more employers will be better able to administer (and sustain) the Mandate. *See* 86 Fed. Reg. 61,402, 61,403 ("OSHA seeks information about the ability of employers with fewer than 100 employees to implement COVID-19 vaccination and/or testing programs."). That may be true. But this kind of thinking belies the premise that any of this is truly an *emergency*. Indeed, underinclusiveness of this sort is often regarded as a telltale sign that the government's interest in enacting a liberty-restraining pronouncement is not in fact "compelling." *Cf. Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 542–46 (1993) (city's ban on religious animal sacrifice but corresponding allowance of other activities similarly endangering public health belied its purportedly "compelling" interest in safe animal disposal practices). The underinclusive nature of the Mandate implies that the Mandate's true purpose is not to enhance workplace safety, but instead to ramp up vaccine uptake by any means necessary.[19]

[19] The Mandate is also underinclusive in the solutions it proposes. Indeed, even in its fullest force, the Mandate cannot prevent vaccinated employees from spreading the virus in the workplace, or prevent unvaccinated employees from spreading the virus in between weekly tests.

(e)

If the deficiencies we've already covered aren't enough, other miscellaneous considerations seal the Mandate's fate. For one, "[t]he Agency cannot use its ETS powers as a stop-gap measure," *Asbestos Info.*, 727 F.2d at 422, but concedes that that is precisely what the Mandate is intended to do here. *See* 86 Fed. Reg. 61,402, 61,434–35 (admitting that "[c]rafting a multi-layered standard that is comprehensive and feasible for all covered work settings, including mixed settings of vaccinated and unvaccinated workers, is an extraordinarily challenging and complicated undertaking, yet the grave danger that COVID-19 poses to unvaccinated workers obliges the agency to act as quickly as possible"). For another, courts have consistently recognized that the "protection afforded to workers [by an ETS] should outweigh the economic consequences to the regulated industry," *Asbestos Info.*, 727 F.2d at 423, but for all the reasons we've previously noted, the Mandate flunks a cost-benefit analysis here.

(f)

It lastly bears noting that the Mandate raises serious constitutional concerns that either make it more likely that the petitioners will succeed on the merits, or at least counsel against adopting OSHA's broad reading of § 655(c) as a matter of statutory interpretation.

First, the Mandate likely exceeds the federal government's authority under the Commerce Clause because it regulates noneconomic inactivity that falls squarely within the States' police power. A person's choice to remain unvaccinated and forgo regular testing is noneconomic inactivity. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 522 (2012) (Roberts, C.J., concurring); *see also id.* at 652–53 (Scalia, J., dissenting). And to mandate that a person receive a vaccine or undergo testing falls squarely within the States' police power. *Zucht v. King*, 260 U.S. 174, 176 (1922) (noting that precedent had long "settled that

it is within the police power of a state to provide for compulsory vaccination"); *Jacobson v. Massachusetts*, 197 U.S. 11, 25–26 (1905) (similar). The Mandate, however, commandeers U.S. employers to compel millions of employees to receive a COVID-19 vaccine or bear the burden of weekly testing. 86 Fed. Reg. 61,402, 61,407, 61,437, 61,552. The Commerce Clause power may be expansive, but it does not grant Congress the power to regulate noneconomic inactivity traditionally within the States' police power. *See Sebelius*, 567 U.S. at 554 (Roberts, C.J., concurring) ("People, for reasons of their own, often fail to do things that would be good for them or good for society. Those failures—joined with the similar failures of others—can readily have a substantial effect on interstate commerce. Under the Government's logic, that authorizes Congress to use its commerce power to compel citizens to act as the Government would have them act."); *see also Bond v. United States*, 572 U.S. 844, 854 (2014) ("The States have broad authority to enact legislation for the public good—what we have often called a 'police power.' . . . The Federal Government, by contrast, has no such authority. . . ." (citations omitted)). Indeed, the courts "*always* have rejected readings of the Commerce Clause . . . that would permit Congress to exercise a police power." *United States v. Lopez*, 514 U.S. 549, 584 (1995) (Thomas, J., concurring). In sum, the Mandate would far exceed current constitutional authority.

Second, concerns over separation of powers principles cast doubt over the Mandate's assertion of virtually unlimited power to control individual conduct under the guise of a workplace regulation. As Judge Duncan points out, the major questions doctrine confirms that the Mandate exceeds the bounds of OSHA's statutory authority. Congress must "speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (cleaned up). The Mandate derives its authority from an old statute employed in a

novel manner,[20] imposes nearly $3 billion in compliance costs, involves broad medical considerations that lie outside of OSHA's core competencies, and purports to definitively resolve one of today's most hotly debated political issues. *Cf. MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 (1994) (declining to hold that the FCC could eliminate telecommunications rate-filing requirements); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000) (declining to hold that the FDA could regulate cigarettes); *Gonzales v. Oregon*, 546 U.S. 243, 262 (2006) (declining to allow DOJ to ban physician-assisted suicide). There is no clear expression of congressional intent in § 655(c) to convey OSHA such broad authority, and this court will not infer one. Nor can the Article II executive breathe new power into OSHA's authority—no matter how thin patience wears.

At the very least, even if the statutory language were susceptible to OSHA's broad reading—which it is not—these serious constitutional concerns would counsel this court's rejection of that reading. *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018).

* * *

Accordingly, the petitioners' challenges to the Mandate show a great likelihood of success on the merits, and this fact weighs critically in favor of a stay.

B.

It is clear that a denial of the petitioners' proposed stay would do them irreparable harm. For one, the Mandate threatens to substantially burden the

[20] Here, it is simply unlikely that Congress assigned authority over such a monumental policy decision to OSHA—hard hats and safety goggles, this is not.

liberty interests[21] of reluctant individual recipients put to a choice between their job(s) and their jab(s). For the individual petitioners, the loss of constitutional freedoms "for even minimal periods of time . . . unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.").

Likewise, the companies seeking a stay in this case will also be irreparably harmed in the absence of a stay, whether by the business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, the diversion of resources necessitated by the Mandate, or by OSHA's plan to impose stiff financial penalties on companies that refuse to punish or test unwilling employees. The Mandate places an immediate and irreversible imprint on all covered employers in America, and "complying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *See Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment)).

The States, too, have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach.

C.

In contrast, a stay will do *OSHA* no harm whatsoever. Any interest OSHA may claim in enforcing an unlawful (and likely unconstitutional) ETS is illegitimate. Moreover, any abstract "harm" a stay might cause the Agency

[21] Not to mention the free religious exercise of certain employees. *See* U.S. CONST. amend. I; *cf. Holt v. Hobbs*, 574 U.S. 352, 361 (2015).

pales in comparison and importance to the harms the absence of a stay threatens to cause countless individuals and companies.

D.

For similar reasons, a stay is firmly in the public interest. From economic uncertainty to workplace strife, the mere specter of the Mandate has contributed to untold economic upheaval in recent months. Of course, the principles at stake when it comes to the Mandate are not reducible to dollars and cents. The public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions according to their own convictions—even, or perhaps *particularly*, when those decisions frustrate government officials.

* * *

The Constitution vests a limited legislative power in Congress. For more than a century, Congress has routinely used this power to delegate policymaking specifics and technical details to executive agencies charged with effectuating policy principles Congress lays down. In the mine run of cases—a transportation department regulating trucking on an interstate highway, or an aviation agency regulating an airplane lavatory—this is generally well and good. But health agencies do not make housing policy, and occupational safety administrations do not make health policy. *Cf. Ala. Ass'n of Realtors*, 141 S. Ct. at 2488–90. In seeking to do so here, OSHA runs afoul of the statute from which it draws its power and, likely, violates the constitutional structure that safeguards our collective liberty.

For these reasons, the petitioners' motion for a stay pending review is GRANTED. Enforcement of the Occupational Safety and Health Administration's "COVID-19 Vaccination and Testing; Emergency

Temporary Standard"[22] remains STAYED pending adequate judicial review of the petitioners' underlying motions for a permanent injunction.[23]

In addition, IT IS FURTHER ORDERED that OSHA take no steps to implement or enforce the Mandate until further court order.

[22] 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928).

[23] The Clerk of Court shall ensure that this order applies with equal force to all related motions consolidated into this case in accordance with the court's November 6, 2021 order.

STUART KYLE DUNCAN, *Circuit Judge*, concurring:

In addition to the many reasons ably identified by Judge Engelhardt's opinion, I underscore one reason why these challenges to OSHA's unprecedented mandate are virtually certain to succeed.

Courts "expect Congress to speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2489 (2021) (quoting *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). OSHA's rule reaches "two-thirds of all private-sector workers in the nation."86 Fed. Reg. 61,402, 61,403 (Nov. 5, 2021). It compels covered employers to (1) make employees get vaccinated or get weekly tests at their expense and wear masks; (2) "remove" non-complying employees; (3) pay per-violation fines; and (4) keep records of employee vaccination or testing status. 86 Fed. Reg. at 61,402–03, 61,551–54; 29 U.S.C. § 666. OSHA invokes no statute expressly authorizing the rule. Instead, OSHA issued it under an emergency provision addressing workplace "substances," "agents," or "hazards" that it has used only ten times in the last 50 years and never to mandate vaccines. 86 Fed. Reg. at 61,403; *see* 29 U.S.C. § 655(c)(1).

Whether Congress could enact such a sweeping mandate under its interstate commerce power would pose a hard question. *See NFIB v. Sebelius*, 567 U.S. 519, 549–61 (2012). Whether OSHA can do so does not.

I concur in granting a stay.

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[8]

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals or comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide a two-dose regimen for individuals aged 12 through 15 years, or

to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[11] to emergency response stakeholders[12] as directed by the U.S.

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[9] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA.

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[11] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[12] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[13] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

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official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[13] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and

under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[14]

[14] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that

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processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise).

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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DOUGLAS J. PETERSON
ATTORNEY GENERAL

No. 21-017
STATE OF NEBRASKA
OFFICIAL
OCT 14 2021
DEPT. OF JUSTICE

SUBJECT: Prescription of Ivermectin or Hydroxychloroquine as Off-Label Medicines for the Prevention or Treatment of Covid-19

REQUESTED BY: Dannette R. Smith
Chief Executive Officer
Nebraska Department of Health and Human Services

WRITTEN BY: Douglas J. Peterson, Attorney General
James A. Campbell, Solicitor General
Mindy L. Lester, Assistant Attorney General

INTRODUCTION

On September 16, 2021, you requested our opinion on whether it would be "deemed unlawful or otherwise subject to discipline under [Neb. Rev. Stat. § 38-186] for an appropriately licensed health care provider, once informed patient consent has been appropriately obtained, to prescribe" ivermectin, hydroxychloroquine, or other "off label use" medications "for the treatment or prevention of COVID-19." You requested this opinion in your role as Chief Executive Officer of the Nebraska Department of Health and Human Services ("Department"). Neb. Rev. Stat. § 84-205(4) gives you, as the head of an executive department, the authority to ask our office's opinion on legal questions like this one.

The Department, acting through its Division of Public Health, enforces the Nebraska Uniform Credentialing Act ("UCA"). The purpose of the UCA is to protect public

health, safety, and welfare.[1] One way in which the Department protects the public is by investigating complaints alleging that licensed healthcare professionals have committed UCA violations.[2] After the Department completes an investigation, it refers the matter to the appropriate professional board to consider and make a recommendation to the Attorney General. Neb. Rev. Stat. § 38-186 then gives the Attorney General the authority to file a petition for discipline against the healthcare provider if such action is warranted.

You indicate in your request that "[c]onsumers and health care providers have been and continue to be inundated with information and opinions[] regarding COVID-19 treatment and prevention." You also note that due to the "sheer volume" of conflicting information, questions have been raised "regarding the permissibility of certain medications for the treatment or prevention of COVID-19." This observation is consistent with questions that our office has received from constituents and discussions that our office has witnessed at some of the professional boards' meetings.

After receiving your question and conducting our investigation, we have found significant controversy and suspect information about potential COVID-19 treatments. A striking example features one of the world's most prestigious medical journals—the Lancet. In the middle of the COVID-19 pandemic, the Lancet published a paper denouncing hydroxychloroquine as dangerous.[3] Yet the reported statistics were so flawed that journalists and outside researchers immediately began raising concerns.[4] Then after one of the authors refused to provide the analyzed data, the paper was retracted,[5] but not before many countries stopped using hydroxychloroquine and trials were cancelled or interrupted. The Lancet's own editor in chief admitted that the paper was a "fabrication," "a monumental fraud,"[6] and "a shocking example of research misconduct in the middle of

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1 Neb. Rev. Stat. § 38-128(1).

2 Neb. Rev. Stat. § 38-1,124.

3 Mandeep R. Mehra et al., *Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet (May 22, 2020), *available at* https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931180-6 (last visited Oct. 14, 2021).

4 Melissa Davey, *Questions raised over hydroxychloroquine study which caused WHO to halt trials for Covid-19*, The Guardian (May 27, 2020), *available at* https://www.theguardian.com/science/2020/may/28/questions-raised-over-hydroxychloroquine-study-which-caused-who-to-halt-trials-for-covid-19 (last visited Oct. 14, 2021).

5 Sarah Boseley & Melissa Davey, *Covid-19: Lancet retracts paper that halted hydroxychloroquine trials*, The Guardian (Jun. 4, 2020), *available at* https://www.theguardian.com/world/2020/jun/04/covid-19-lancet-retracts-paper-that-halted-hydroxychloroquine-trials (last visited Oct. 14, 2021).

6 Roni Caryn Rabin, *The Pandemic Claims New Victims: Prestigious Medical Journals*, New York Times (Jun. 14, 2020), *available at* https://www.nytimes.com/2020/06/14/health/virus-journals.html (last visited Oct. 14, 2021).

a global health emergency."[7] When fraudulent information is published in a leading medical journal, it understandably leads to skepticism in some physicians and members of the public. Mindful of these concerns about misunderstandings and mistrust, we have drafted a rather lengthy opinion that aims to address the public confusion and outline the relevant scientific literature that supports our legal conclusions.

At the outset, we pause to delineate the parameters of this opinion. The question presented asked about ivermectin, hydroxychloroquine, and other drugs used "off label"—that is, for a purpose other than the specific use approved by the U.S. Food and Drug Administration ("FDA"). To enable us to respond in a timely manner, we have confined our discussion to ivermectin and hydroxychloroquine only. But in doing so, we do not mean to rule out the possibility that other off-label drugs might show promise—either now or in the future—as a prophylaxis or treatment against COVID-19. Also, because our investigation has revealed that physicians who currently use hydroxychloroquine for COVID-19 do so as either a prophylaxis or an early treatment for outpatients (as opposed to a late treatment in hospitalized patients), we will confine our consideration of hydroxychloroquine to those two uses. In addition, we note that there are treatment options the FDA has approved, either through an Emergency Use Authorization ("EUA") or through the regular FDA drug-approval process, for COVID-19 prophylaxis or treatment. These include monoclonal antibodies, vaccines, and remdesivir. We do not take any position on those options because they are outside the scope of the question asked.

In the end, as we explain below, we find that the available data does not justify filing disciplinary actions against physicians simply because they prescribe ivermectin or hydroxychloroquine to prevent or treat COVID-19. If, on the other hand, healthcare providers neglect to obtain informed consent, deceive their patients, prescribe excessively high doses, fail to check for contraindications, or engage in other misconduct, they might be subject to discipline. But based on the evidence that currently exists, the mere fact of prescribing ivermectin or hydroxychloroquine for COVID-19 will not result in our office filing disciplinary actions. While our terminology throughout this opinion focuses on physicians prescribing these medicines, what we conclude necessarily applies to other licensed healthcare professionals who prescribe, participate in, or otherwise assist with a treatment plan utilizing these medications.

ANALYSIS

1. The Nebraska Uniform Credentialing Act and Other Relevant Law

The UCA was enacted by the legislature to license and regulate persons and businesses that provide healthcare and health-related services.[8] The UCA was adopted

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7 Boseley & Davey, *supra*.

8 Neb. Rev. Stat. §§ 38-102 & 38-104.

to protect public health, safety, and welfare, and to provide for the efficient, adequate, and safe practice of credentialed persons and businesses.[9] "It is the intent of the Legislature," the UCA explains, "that quality health care services and human services be provided to the public" and "that professionals be regulated by the state only when it is demonstrated that such regulation is in the best interest of the public."[10]

The UCA grants the Director of Public Health of the Department's Division of Public Health the authority to deny a credential, refuse a credential renewal, or discipline a credential holder, although the Chief Medical Officer (if one is appointed) shall perform the Director's duties for decisions in contested administrative cases.[11] The Department must provide "the Attorney General with a copy of all complaints it receives and advise the Attorney General of investigations it makes" regarding possible violations of the UCA.[12] Following review and recommendation from the appropriate professional health board, the Attorney General must then determine whether the credential holder has violated any statutes or regulations and decide whether to proceed with administrative action.[13]

If the Attorney General determines that a violation has occurred, he "shall" file a petition for disciplinary action with the Department.[14] The Attorney General cannot prevail in disciplinary proceedings against a licensed healthcare professional unless he proves the claim by clear and convincing evidence.[15]

The grounds for disciplinary action are set forth in Neb. Rev. Stat. § 38-178 and include, among other things, acting with "gross incompetence or gross negligence," practicing in "a pattern of incompetent or negligent conduct," or engaging in "unprofessional conduct" as set forth in Neb. Rev. Stat. § 38-179.[16] Gross incompetence is a very high standard; it occurs only when there is "such an extreme deficiency on the part of a physician in the basic knowledge and skill necessary for diagnosis and treatment that one may reasonably question his or her ability to practice medicine at the threshold level of

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9 Neb. Rev. Stat. § 38-103.

10 Neb. Rev. Stat. § 38-128(1).

11 Neb. Rev. Stat. §§ 38-176(1) & 38-1,101.

12 Neb. Rev. Stat. § 38-1,107(1).

13 Neb. Rev. Stat. §§ 38-1,107 & 38-1,108.

14 Neb. Rev. Stat. § 38-186.

15 *Poor v. State*, 266 Neb. 183, 190, 663 N.W.2d 109, 115 (2003); *Davis v. Wright*, 243 Neb. 931, 936-37, 503 N.W.2d 814, 818 (1993).

16 Neb. Rev. Stat. § 38-178(6), (24).

professional competence."[17] Neb. Rev. Stat. § 38-179 generally defines unprofessional conduct as a "departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or the ethics of the profession, regardless of whether a person, consumer, or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest."[18] Along these same lines, the regulation governing physicians states that unprofessional conduct includes:

> [c]onduct or practice outside the normal standard of care in the State of Nebraska which is or might be harmful or dangerous to the health of the patient or the public, not to include a single act of ordinary negligence.[19]

Healthcare providers do not violate the standard of care when they "select between two reasonable approaches to . . . medicine."[20] Regulations also indicate that physicians may utilize reasonable "investigative or unproven therapies" that reflect a reasonable approach to medicine so long as physicians obtain "written informed patient consent."[21] "Informed consent concerns a doctor's duty to inform his or her patient," and it includes telling patients about "the nature of the pertinent ailment or condition, the risks of the proposed treatment or procedure, and the risks of any alternative methods of treatment, including the risks of failing to undergo any treatment at all."[22] Regulations require physicians "to keep and maintain" records that disclose the "advice and cautionary warnings provided to the patient."[23]

Prescribing medicines for off-label use—that is, for some purpose other than the use approved by the FDA—often falls within the standard of care. Indeed, "[o]ff-label use is legal, common, and necessary,"[24] and "[c]ourts have repeatedly recognized the propriety of off-label use."[25] This includes the U.S. Court of Appeals for the Eighth Circuit, which has acknowledged that "[d]octors may prescribe an FDA-approved drug for

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17 *Langvardt v. Horton*, 254 Neb. 878, 895, 581 N.W.2d 60, 70-71 (1998).

18 Neb. Rev. Stat. § 38-179.

19 172 Neb. Admin. Code § 88-009(Q).

20 *Whittle v. Dep't of Health & Hum. Servs.*, 309 Neb. 695, 721-22, 962 N.W.2d 339, 356-57 (2021).

21 172 Neb. Admin. Code § 88-009(B).

22 *Curran v. Buser*, 271 Neb. 332, 337, 711 N.W.2d 562, 568 (2006) (citations omitted).

23 172 Neb. Admin. Code § 88-009(B).

24 James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76 (1998) (capitalization omitted).

25 *Id.* (collecting cases).

nonapproved uses."[26] And the U.S. Supreme Court, in an analogous context, has affirmed that "'off-label' usage of medical devices" is an "accepted and necessary" practice.[27] Even the FDA recognizes that off-label use is legitimate: it has said for many decades that once it approves a drug, "a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."[28] Expanding on that point, the FDA has explained that "healthcare providers generally may prescribe [a] drug for an unapproved use when they judge that it is medically appropriate for their patient."[29] Nothing in the federal Food, Drug, and Cosmetic Act ("FDCA") "limit[s] the manner in which a physician may use an approved drug."[30]

Based on these principles, we conclude that governing law allows physicians to use FDA-approved medicines that are unproven for a particular off-label use so long as (1) reasonable medical evidence supports that use and (2) a patient's written informed consent is obtained. In the context of this ever-changing global pandemic, we note that it is appropriate to consider medical evidence outside of Nebraska and to give physicians who obtain informed consent an added measure of deference on their assessment of the available medical evidence.

2. COVID-19 and SARS-CoV-2

The disease known as COVID-19 and the virus that causes it—SARS-CoV-2—took the world by storm in late 2019 and early 2020. While there is still so much that the medical community does not know about SARS-CoV-2 and COVID-19, it is widely recognized that COVID-19 is a multifaceted disease. "[A]dults with SARS-CoV-2 infection can be grouped" into at least three different categories depending on the progression of their disease.[31] The first group has an asymptomatic or presymptomatic infection, meaning that those individuals have "test[ed] positive for SARS-CoV-2" but "have no symptoms

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[26] *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514 n.3 (8th Cir. 1996).

[27] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

[28] FDA Drug Bulletin at 5 (Apr. 1982), *available at* https://play.google.com/books/reader?id=3f3YC3Gw6sEC&pg=GBS.PA6&hl=en (last visited Oct. 14, 2021).

[29] U.S. Food & Drug Administration, Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (last visited Oct. 14, 2021).

[30] FDA Drug Bulletin, *supra*, at 5. Because the question posed to us asks about prescribing drugs for off-label use, any view on the legality of efforts to market drugs for off-label use is outside the scope of this opinion.

[31] National Institutes of Health, Clinical Spectrum of SARS-CoV-2 Infection, COVID-19 Treatment Guidelines (Apr. 21, 2021), *available at* https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/ (last visited Oct. 14, 2021).

that are consistent with COVID-19."[32] A second group experiences a mild illness that manifests itself through "any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell)" but does not include "shortness of breath, dyspnea, or abnormal chest imaging."[33] And a third group suffers from a more severe illness marked by "evidence of lower respiratory disease" and deficient "oxygen saturation" levels.[34] When people in this third category reach a critical level, they often "have respiratory failure, septic shock, and/or multiple organ dysfunction."[35]

A recently published paper on COVID-19 recognized that "for reasons that are yet to be clarified, early treatment has not been emphasized" in Western countries like the United States.[36] Despite this, many healthcare providers in the United States advocate for early treatment, particularly for high-risk patients. In fact, scores of treating and academic physicians have published papers in well-respected journals like the American Journal of Medicine explaining that the "multifaceted pathophysiology of life-threatening COVID-19 illness . . . warrants early interventions"[37] and encouraging "outpatient treatment of the illness with the aim of preventing hospitalization or death."[38] Also, a declaration of the International Alliance of Physicians and Medical Scientists—which is apparently signed by over 10,000 physicians and scientists, more than 60 of whom are publicly identified online—supports a doctor's choice to provide early COVID-19 care rather than "advising their patients to simply go home . . . and return when their disease worsens."[39]

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32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.*

36 Matthieu Million et al., *Early combination therapy with hydroxychloroquine and azithromycin reduces mortality in 10,429 COVID-19 outpatients*, 22 Reviews in Cardiovascular Medicine 1063, 1063 (Sept. 2021), https://rcm.imrpress.com/article/2021/2153-8174/2153-8174-22-3-1063.shtml (last visited Oct. 14, 2021).

37 Peter A. McCullough et al., *Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)*, 21 Reviews in Cardiovascular Medicine 517, 518 (Dec. 2020), *available at* https://rcm.imrpress.com/article/2020/2153-8174/RCM2020264.shtml (last visited Oct. 14, 2021) (including 57 co-authors) (hereinafter, "McCullough, *Multifaceted*").

38 Peter A. McCullough et al., *Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection*, 134 American Journal of Medicine 16, 16 (Jan. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7410805/pdf/main.pdf (last visited Oct. 14, 2021) (including 23 co-authors) (hereinafter, "McCullough, *Pathophysiological*").

39 Physicians Declaration, Global COVID Summit, International Alliance of Physicians and Medical Scientists (Sept. 2021), https://doctorsandscientistsdeclaration.org/ (last visited Oct. 14, 2021).

These groups of physicians have established protocols for early treatment, and ivermectin and hydroxychloroquine are staples of those treatments.[40] As discussed in greater detail below, while the scientific literature is continuing to grow, some data suggest that ivermectin- or hydroxychloroquine-based early treatments of COVID-19 can be effective in thwarting hospitalization and death.[41]

3. Ivermectin

A. History of Ivermectin

Researchers discovered ivermectin in the 1970s, and while its first use was to treat parasites in animals, ivermectin has been used in humans since the 1980s.[42] In the early years, ivermectin effectively stymied the scourge of two devastating parasitic diseases—onchocerciasis (also known as river blindness) and lymphatic filariasis—"among poverty-stricken populations throughout the tropics."[43] These are two of the most "disfiguring diseases" that "have plagued the world's poor . . . for centuries."[44] Later, the use of ivermectin was expanded to include "the treatment of scabies and lice."[45]

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40 *E.g.*, McCullough, *Multifaceted*, *supra*, at 519 Table 1 (listing early treatment kits that include both ivermectin and hydroxychloroquine); McCullough, *Pathophysiological*, *supra*, at 18–19 (discussing hydroxychloroquine).

41 *E.g.*, Flavio A. Cadegiani et al., *Early COVID-19 therapy with azithromycin plus nitazoxanide, ivermectin or hydroxychloroquine in outpatient settings significantly improved COVID-19 outcomes compared to known outcomes in untreated patients*, New Microbes and New Infections (Sept. 2021), *available at* https://www.sciencedirect.com/science/article/pii/S2052297521000792 (last visited Oct. 14, 2021) (finding that "the use of nitazoxanide, ivermectin[,] and hydroxychloroquine demonstrated unexpected improvements in COVID-19 outcomes when compared to untreated patients").

42 Andy Crump, *Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations*, 70 The Journal of Antibiotics 495, 495 (2017), *available at* https://www.nature.com/articles/ja201711.pdf (last visited Oct. 14, 2021) (hereinafter, "Crump, *Ivermectin*").

43 *Id.*

44 Andy Crump & Satoshi Ōmura, *Ivermectin, 'wonder drug' from Japan: the human use perspective*, 87 Proceedings of the Japan Academy, Series B, Physical and biological sciences 13, 13 (2011), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/pdf/pjab-87-013.pdf (last visited Oct. 14, 2021).

45 Andrew Bryant et al., *Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines*, 28 American Journal of Therapeutics 434, 435 (Jul./Aug. 2021), *available at* https://journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin_for_prevention_and_treatment_of.7.aspx (last visited Oct. 14, 2021) (hereinafter, "Bryant, *Ivermectin*").

Given its track record as a medicine for humans, ivermectin has long since been "approved as an antiparasitic" by the World Health Organization (WHO) and the FDA.[46] The WHO has also recognized ivermectin as one of its "Essential Medicines."[47] Further recognizing the importance of this drug, in 2015 its discoverers won the Nobel Prize in Medicine for their work in uncovering it and bringing it to market.[48]

In the decade leading up to the COVID-19 pandemic, studies began to show ivermectin's surprising versatility. By 2017, ivermectin had "demonstrate[d] antiviral activity against several RNA viruses by blocking the nuclear trafficking of viral proteins."[49] One recent systematic review cited more than a handful of studies to "demonstrate that ivermectin has antiviral properties against an increasing number of RNA viruses, including influenza, *Zika*, HIV, [and] *Dengue*."[50] And another review summarized the "antiviral effects of ivermectin" demonstrated through "studies over the past 50 years."[51]

Before the pandemic, scholarly literature had also recognized ivermectin's "anti-inflammatory capacity."[52] Doctors thus have been using ivermectin to treat "rosacea, a chronic inflammatory disease," that manifests itself as a reddening of the face, and the FDA has approved ivermectin for that purpose.[53] Ivermectin's ability to "curb inflammation," one reviewer wrote, may also "be useful in treating . . . inflammatory airway diseases."[54] Summing it up, that same reviewer recognized that "ivermectin is continuing

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46 *Id.*

47 *Id.*

48 The Nobel Prize, Press Release for The Nobel Prize in Physiology or Medicine 2015 (Oct. 5, 2015), https://www.nobelprize.org/prizes/medicine/2015/press-release/ (last visited Oct. 14, 2021).

49 Crump, *Ivermectin*, *supra*, at 500.

50 Pierre Kory et al., *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, 28 American Journal of Therapeutics 299, 301 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8088823/ (last visited Oct. 14, 2021).

51 Fatemeh Heidary & Reza Gharebaghi, *Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen*, 73 The Journal of Antibiotics 593, 593 (2020), *available at* https://www.nature.com/articles/s41429-020-0336-z.pdf (last visited Oct. 14, 2021) ("Several studies reported antiviral effects of ivermectin on RNA viruses . . . . Furthermore, there are some studies showing antiviral effects of ivermectin against DNA viruses . . . .").

52 Crump, *Ivermectin*, *supra*, at 499.

53 Leon H. Kircik et al., *Over 25 Years of Clinical Experience With Ivermectin: An Overview of Safety for an Increasing Number of Indications*, 15 Journal of Drugs in Dermatology 325, 325 (Mar. 2016), *available at* https://jddonline.com/articles/dermatology/S1545961616P0325X (last visited Oct. 14, 2021).

54 Crump, *Ivermectin*, *supra*, at 499; *see also* Arianna Portmann-Baracco et al., *Antiviral and anti-inflammatory properties of ivermectin and its potential use in Covid-19*, 56 Archivos De Bronconeumologia

to surprise and excite scientists, offering more and more promise to help improve global public health by treating a diverse range of diseases."[55]

For more than three decades, ivermectin has also shown itself to be very safe. Indeed, the National Institutes of Health ("NIH") recognize that "ivermectin has been widely used and is generally well tolerated."[56] One recent systematic review similarly states that "ivermectin at the usual doses . . . is considered extremely safe for use in humans."[57] Other studies have noted that the medicine "has an established safety profile for human use,"[58] and it "provide[s] a high margin of safety for a growing number of indications."[59] Notably, a December 2018 WHO-supported application to add ivermectin as an essential medicine for scabies reviewed the data and concluded that the adverse events associated with ivermectin are "primarily minor and transient."[60]

The available data support this conclusion. The WHO's VigiAccess database, which compiles adverse drug reactions from throughout the world, breaks down the reported side effects for drugs into different categories.[61] The largest reported categories for ivermectin include skin issues, headaches, dizziness, and gastrointestinal disturbances such as diarrhea and nausea.[62] The NIH confirms that ivermectin's primary adverse side effects "include dizziness, pruritis [itchy skin], nausea, or diarrhea."[63] And

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831, 831 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578741/pdf/main.pdf (last visited Oct. 14, 2021) ("Ivermectin has a demonstrated anti-inflammatory effect *in vivo* and *in vitro*").

55 Crump, *Ivermectin*, *supra*, at 495.

56 National Institutes of Health, COVID-19 Treatment Guidelines: Ivermectin, https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/ (last visited Oct. 14, 2021) (hereinafter, "NIH, COVID-19 and Ivermectin").

57 Bryant, *Ivermectin*, *supra*, at 435.

58 Leon Caly et al., *The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro*, Antiviral Research 178 at 3 (June 2020), *available at* https://www.sciencedirect.com/science/article/pii/S0166354220302011 (last visited Oct. 14, 2021).

59 Kircik, *Ivermectin*, *supra*, at 325.

60 WHO Expert Committee on the Selection and Use of Essential Medicines: Application for inclusion of ivermectin on the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) for the indication of Scabies at 19 (Dec. 2018), *available at* https://www.who.int/selection_medicines/committees/expert/22/applications/s6.6_ivermectin.pdf (last visited Oct. 14, 2021).

61 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

62 *Id.*

63 NIH, COVID-19 and Ivermectin, *supra*.

a recent review of ivermectin similarly describes the common side effects as "itching, rash, swollen lymph nodes, joint pain[], fever, and headache."[64]

The data show not only that the adverse side effects are minor, but also that the percentage of people who report experiencing any adverse events is vanishingly small. The latest statistics available through VigiAccess report only 5,674 adverse drug reactions from ivermectin between 1992 and October 13, 2021.[65] This number is incredibly low considering that "more than 3.7 billion doses" of ivermectin have been administered to humans worldwide since the 1980s.[66]

To illustrate the safety of ivermectin, compare its VigiAccess report to that of remdesivir, an FDA-approved treatment for COVID-19.[67] Remdesivir was not released for widespread use until 2020. Yet in the short period of time that it has been on the market, people have reported at least 7,491 adverse drug reactions on VigiAccess, more than ivermectin has registered over the last 30 years.[68] What's more, serious adverse reactions from remdesivir are reported in high numbers. For example, in less than two years, those who have used remdesivir have reported over 560 deaths, 550 serious cardiac disorders (such as bradycardia and cardiac arrest), and 475 acute kidney injuries.[69] Since that safety profile is sufficient to retain FDA approval, ivermectin's safety record cannot reasonably be questioned.

B. Ivermectin and COVID-19

As discussed above, ivermectin had shown its antiviral and anti-inflammatory properties long before the pandemic began. So when COVID-19 began to spread across the globe, some in the medical community quickly identified ivermectin as a potential drug for the prevention and treatment of COVID-19. Initially, a group of researchers found that ivermectin significantly inhibited replication of SARS-CoV-2 in cell cultures.[70] Dismissing

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64 Kory, *supra*, at 314.

65 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

66 Morimasa Yagisawa et al., *Global trends in clinical studies of ivermectin in COVID-19*, 74 The Japanese Journal of Antibiotics 44, 46 (Mar. 2021), *available at* http://jja-contents.wdc-jp.com/pdf/JJA74/74-1-open/74-1_44-95.pdf (last visited Oct. 14, 2021).

67 U.S. Food and Drug Administration, *FDA Approves First Treatment for COVID-19* (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19 (last visited Oct. 14, 2021).

68 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

69 *Id.*

70 Caly, *supra*, at 1.

that finding, ivermectin doubters argued that too much of the drug would be needed to achieve this antiviral activity in humans.[71] But peer-reviewed models undermined those concerns by showing that the predicted accumulation of ivermectin in the lungs—the site in the body where the medicine is most needed—would be over 10 times higher than necessary for antiviral activity.[72] In layman's terms, these models indicated that an effective level of the medicine can be reached in lung tissue without creating toxicity in the blood. Plus, other pro-ivermectin doctors have explained that the amount of the drug "required for an effect in cell culture models bear[s] little resemblance to human physiology" because cell cultures lack "an active immune system working synergistically with" the medicine.[73]

The doctors who believed that ivermectin could be effective against COVID-19 also identified its anti-inflammatory properties as an important countermeasure to the disease. One reason why COVID-19 progresses to its severe phase, many believe, is "the provocation of an overwhelming and injurious inflammatory response."[74] Thus, ivermectin's anti-inflammatory effects suggest that it can help COVID-19 patients as the disease worsens.

i. Ivermectin Studies and Meta-analyses

Since the COVID-19 pandemic began, researchers have conducted over 20 randomized controlled trials (RCTs) and more observational trials to evaluate ivermectin's effectiveness in the prevention and treatment of COVID-19.[75] Many of those trials showed promise. On the question of COVID-19 prevention, the Shouman study out of Egypt—a RCT—evaluated ivermectin as a potential prophylaxis for close family members of COVID-19 patients.[76] The test group included 203 family members who took

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71 Virginia D. Schmith et al., *The Approved Dose of Ivermectin Alone is not the Ideal Dose for the Treatment of COVID-19*, 108 Clinical Pharmacology & Therapeutics 762, 762 (Oct. 2020), *available at* https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1002/cpt.1889 (last visited Oct. 14, 2021).

72 Usman Arshad et al., *Prioritization of Anti-SARS-Cov-2 Drug Repurposing Opportunities Based on Plasma and Target Site Concentrations Derived from their Established Human Pharmacokinetics*, 108 Clinical Pharmacology and Therapeutics 775, 785 (Oct. 2020), *available at* https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1002/cpt.1909 (last visited Oct. 14, 2021).

73 Kory, *supra*, at 301.

74 *Id.*

75 Bryant, *Ivermectin*, *supra*, at 435.

76 Waheed M. Shouman et al., *Use of Ivermectin as a Potential Chemoprophylaxis for COVID-19 in Egypt: A Randomised Clinical Trial*, 15 Journal of Clinical and Diagnostic Research 27, 27 (Feb. 2021), *available at* https://www.jcdr.net/articles/PDF/14529/46795_CE[Ra]_F(Sh)_PF1(SY_OM)_PFA_(OM)_PN(KM).pdf (last visited Oct. 14, 2021).

ivermectin, and only 15 of them (7.4%) developed COVID-19.[77] Compare that to the 101 family members in the control group, 59 of whom (58.4%) tested positive during the study.[78] These outcomes prompted the research team to conclude that ivermectin is "a promising, effective[,] and safe chemoprophylactic drug in management of COVID-19."[79] Also, the Behera study in India tested ivermectin as a prophylaxis in a group of 3,532 healthcare workers.[80] Of the 2,199 workers who took two doses of ivermectin prophylaxis three days apart, only 45 (2%) tested positive for COVID-19.[81] But of the 1,147 workers who did not take ivermectin, 133 (11.6%) contracted the disease.[82] Behera's team thus announced that two doses of ivermectin "as chemoprophylaxis among [healthcare workers] reduced the risk of COVID-19 infection by 83% in the following month."[83]

Moving beyond ivermectin's role as a prophylaxis, other studies have demonstrated its potential as a COVID-19 treatment. The Mahmud study—a RCT that explored ivermectin as an early treatment for 363 individuals—concluded that "[p]atients with mild-to-moderate COVID-19 infection treated with ivermectin plus doxycycline recovered earlier, were less likely to progress to more serious disease, and were more likely to be COVID-19 negative . . . on day 14."[84] And Niaee's research team found that ivermectin can help even hospitalized patients.[85] That group conducted a "randomized, double-blind, placebo-controlled, multicenter clinical trial" with 180 hospitalized patients diagnosed with COVID-19.[86] They concluded that ivermectin "reduces the rate of

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77 *Id.*

78 *Id.*

79 *Id.*

80 Priyamadhaba Behera et al., *Prophylactic Role of Ivermectin in Severe Acute Respiratory Syndrome Coronavirus 2 Infection Among Healthcare Workers*, Cureus, at 1 (Aug. 2021), *available at* https://assets.cureus.com/uploads/original_article/pdf/64807/20210904-4912-omcmtf.pdf (last visited Oct. 14, 2021).

81 *Id.* at 5.

82 *Id.*

83 *Id.* at 1.

84 Reaz Mahmud et al., *Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial*, Journal of International Medical Research 49(5) (Apr. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8127799/pdf/10.1177_03000605211013550.pdf (last visited Oct. 14, 2021).

85 Morteza Shakhsi Niaee et al., *Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: A randomized multi-center clinical trial*, 14 Asian Pacific Journal of Tropical Medicine 266, 266 (2021), *available at* https://www.apjtm.org/temp/AsianPacJTropMed146266-5371482_145514.pdf (last visited Oct. 14, 2021).

86 *Id.*

mortality . . . and duration of hospitalization in adult COVID-19 patients," and "[t]he improvement of other clinical parameters showed that the ivermectin, with a wide margin of safety, had a high therapeutic effect on COVID-19."[87]

As the data accumulated, scholars began conducting and publishing meta-analyses of the available studies. One such analysis—the Bryant review—focused on 24 total RCTs involving 3,406 participants and found "with moderate certainty that ivermectin treatment in COVID-19 provides a significant survival benefit."[88] It also concluded that "[u]sing ivermectin early in the clinical course may reduce numbers progressing to severe disease" and that "[t]he apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally."[89] Following Bryant's publication of his team's review, the Elgazzar study—one of the RCTs included in the meta-analysis—was questioned and is now under review. This prompted Bryant's team to reanalyze the data without the Elgazzar study, and that review still found "a clear result, showing a 49% reduction in mortality in favor of ivermectin."[90]

Another meta-analysis known as the Popp review has reached more skeptical conclusions. That analysis, which excluded some of the RCTs that Bryant considered, evaluated only 14 studies with 1,678 participants and determined that the "completed studies are small and few are considered high quality."[91] Thus, the authors expressed "uncertain[ty] about the efficacy and safety of ivermectin used to treat or prevent COVID-19."[92] Recently, however, the Bryant team critiqued the Popp review, highlighting, among other things, that although "Popp claims to provide a 'complete evidence profile,'" it actually "excludes most of the available evidence."[93]

In further contrast, a third meta-analysis expressed doubt about ivermectin. That one—the Roman review—restricted the pool of RCTs even further, considering only 10

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87 *Id.*

88 Bryant, *Ivermectin*, *supra*, at 451.

89 *Id.* at 435.

90 Andrew Bryant et al., *Letter to the Editor: Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines*, 28 American Journal of Therapeutics 573, 573 (Sept./Oct. 2021), *available at* https://covid19criticalcare.com/wp-content/uploads/2021/09/Response-to-Elgazzar.pdf (last visited Oct. 14, 2021).

91 Maria Popp et al., *Ivermectin for preventing and treating COVID-19*, Cochrane Database of Systematic Reviews, at 2 (July 28, 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8406455/pdf/CD015017.pdf (last visited Oct. 14, 2021).

92 *Id.*

93 Edmund J. Fordham et al., *The uses and abuses of systematic reviews: the case of ivermectin in Covid-19*, OSF Preprints, at 7 (Sept. 3, 2021), *available at* https://osf.io/peqcj/ (last visited Oct. 14, 2021).

of them.[94] After doing this, the authors concluded that ivermectin does "not reduce all-cause mortality, [length of hospital stay], or viral clearance . . . in patients with mostly mild COVID-19."[95] As a result, the researchers announced that ivermectin "is not a viable option to treat patients with COVID-19."[96]

In the days since its publication, the Roman review has drawn some harsh criticism. In particular, the authors of the Bryant review have highlighted four categories of flaws with Roman's work: (1) "mis-reporting of source data," (2) "highly selective study inclusion," (3) "'cherry picking' of data within included studies," and (4) "conclusions that do not follow from the evidence."[97] To illustrate these flaws, consider that Roman's paper initially inverted the treatment and control arms for the Niaee study and thus indicated less mortality in the control group when in fact the opposite was true.[98] Once that error was fixed, the numbers no longer supported the conclusion that ivermectin does "not reduce all-cause mortality."[99] Yet the Roman team did not adjust that statement, and thus its "conclusions are no longer based on the data."[100]

Furthermore, in a letter to the editor of the *American Journal of Therapeutics*, two researchers recently explained that Roman's conclusion of no mortality reduction "is not based on the results of the statistical analysis of the data . . . ; instead, it was based on a somewhat vague and possibly biased subjective assessment of the quality of the trials

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94 Yuani M. Roman et al., *Ivermectin for the treatment of Coronavirus Disease 2019: A systematic review and meta-analysis of randomized controlled trials*, Clinical Infectious Diseases, at 1 (June 28, 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8394824/pdf/ciab591.pdf (last visited Oct. 14, 2021).

95 *Id.*

96 *Id.*

97 Letter from Andrew Bryant et al. to Robert T. Schooley, MD, Editor in Chief, Clinical Infectious Diseases, at 3, *available at* https://covid19criticalcare.com/wp-content/uploads/2021/07/RomanRebuttal_v7_EF_letterhead_ML-1.pdf (last visited Oct. 14, 2021) (hereinafter, "Bryant Letter to Schooley").

98 *Compare* Yuani M. Roman et al., *Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials*, Preprint Version 1, at 27 Figure 2 (May 25, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.05.21.21257595v1.full.pdf (last visited Oct. 14, 2021) (listing the Niaee study as having four deaths in the control arm and 11 in the ivermectin arm), *with* Yuani M. Roman et al., *Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials*, Preprint Version 2, at 27 Figure 2 (May 26, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.05.21.21257595v2.full.pdf (last visited Oct. 14, 2021) (correcting the Niaee study to list 11 deaths in the control arm and four in the ivermectin arm).

99 Bryant Letter to Schooley, *supra*, at 2.

100 *Id.*

themselves."[101] Those researchers conducted their own Bayesian analysis, a method of statistical inference, and found that the "probability for the hypothesis of a causal link between COVID-19 severity, ivermectin, and mortality is over 99%."[102] As they concluded, "[i]n our view, this Bayesian analysis, based on the statistical study data, provides sufficient confidence that ivermectin is an effective treatment for COVID-19 and this belief supports the conclusions of Bryant over those of Roman."[103] Those scholars have since published their full analysis in a paper available online.[104]

Additional supportive evidence for Bryant's conclusions is a non-peer-reviewed website that currently maintains a running list of 64 COVID-19-related ivermectin studies—RCTs and others—which include all the relevant ivermectin studies except the few (such as Elgazzar) whose data have been called into question.[105] Of those 64 studies, 31 are RCTs and 44 have been peer-reviewed.[106] That site posts multiple meta-analyses of different groupings of the data and concludes that "[m]eta analysis using the most serious outcome reported shows" that ivermectin leads to 66% "improvement for early treatment" and an 86% "improvement for . . . prophylaxis."[107] These "[r]esults are very robust," the site reports, because "in worst case exclusion sensitivity analysis 53 of 64 studies must be excluded to avoid finding statistically significant efficacy."[108]

Finally, a recent mini-review of ivermectin and COVID-19 considered the studies analyzing ivermectin's safety specifically in the context of COVID-19 treatments.[109] That mini-review—which was authored by Yale Professor Alessandro D. Santin—observed

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101 Martin Neil & Norman Fenton, *Bayesian Hypothesis Testing and Hierarchical Modeling of Ivermectin Effectiveness*, 28 American Journal of Therapeutics 576, 576 (Sept./Oct. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8415515/pdf/ajt-28-e576.pdf (last visited Oct. 14, 2021).

102 *Id.*

103 *Id.* at 578.

104 Martin Neil & Norman Fenton, Bayesian hypothesis testing and hierarchical modelling of ivermectin effectiveness in treating Covid-19 (Oct. 1, 2021), *available at* https://arxiv.org/ftp/arxiv/papers/2109/2109.13739.pdf (last visited Oct. 14, 2021).

105 Ivermectin for COVID-19: Real-time meta analysis of 64 studies (Oct. 8, 2021), https://ivmmeta.com/ (last visited Oct. 14, 2021).

106 *Id.*

107 *Id.*

108 *Id.*

109 Alessandro D. Santin et al., *Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19*, New Microbes New Infections (Aug. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383101/pdf/main.pdf (last visited Oct. 14, 2021).

that ivermectin "has been safely used in 3.7 billion doses since 1987" and that the medicine has been "used without serious [adverse effects]" in multiple "COVID-19 treatment studies."[110]

The existing ivermectin studies and meta-analyses are subject to vigorous ongoing disputes, and there are large ongoing studies, at least one of which includes the NIH as a collaborator, that will hopefully provide additional clarity.[111] But based on the existing medical literature, we do not find clear and convincing evidence that a physician who prescribes ivermectin for COVID-19 after obtaining informed consent engages in unprofessional conduct or otherwise violates the UCA.

While we find the studies and meta-analyses sufficient to resolve this question, we note that epidemiological evidence—derived by analyzing COVID-related data from various states, countries, or regions—is also instructive in the context of a global pandemic. We highlight just a few examples.

One set of scholars analyzed data comparing the COVID-19 rates of countries that routinely administer ivermectin as a prophylaxis and countries that do not.[112] The research revealed that "countries with routine mass drug administration of prophylactic . . . ivermectin have a significantly lower incidence of COVID-19."[113] This "highly significant" correlation manifests itself not only "in a worldwide context" but also when comparing African countries that regularly administer prophylactic "ivermectin against parasitic infections" and African countries that do not.[114] Based on these results, the researchers surmised that these results "may be connected to ivermectin's ability to inhibit SARS-CoV-2 replication, which likely leads to lower infection rates."[115]

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110 *Id.* at 4.

111 *E.g.*, U.S. National Library of Medicine, ACTIV-6: COVID-19 Study of Repurposed Medications, https://clinicaltrials.gov/ct2/show/NCT04885530?term=activ-6&draw=2&rank=1 (last visited Oct. 14, 2021) (purpose of this trial involving an estimated 15,000 participants is "to evaluate the effectiveness of repurposed medications" that include ivermectin "in reducing symptoms of non-hospitalized participants with mild to moderate COVID-19"); U.S. National Library of Medicine, COVID-OUT: Early Outpatient Treatment for SARS-CoV-2 Infection (COVID-19), https://clinicaltrials.gov/ct2/show/NCT04510194?_term=ivermectin+boulware&draw=2&rank=1 (last visited Oct. 14, 2021) (purpose of this trial involving 1,160 participants is to understand whether ivermectin is superior to other options, including placebo, in "non-hospitalized adults with SARS-CoV-2 disease for preventing Covid-19 disease progression").

112 Martin D. Hellwig & Anabela Maia, *A COVID-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin*, International Journal of Antimicrobial Agents (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7698683/pdf/main.pdf (last visited Oct. 14, 2021).

113 *Id.* at 1.

114 *Id.*

115 *Id.*

More specifically, Peru's COVID-19 statistics, which have been analyzed in pre-print studies and discussed in published ivermectin reviews, are also informative.[116] Peru deployed mass ivermectin-based COVID-19 treatments from April 2020 through November 2020 throughout its 25 states.[117] In ten of those states, a maximal amount of "mass [ivermectin] treatments of COVID-19 were conducted through a broadside, army-led effort, *Mega-Operación Tayta (MOT)*."[118] Fourteen other states had a medium distribution of ivermectin administered at the local level.[119] And one state, Lima, distributed a minimal amount of ivermectin due to restrictive government policies.[120] "The mean reduction in excess deaths 30 days after peak deaths was 74% for the maximal [ivermectin] distribution group, 53% for the medium group[,] and 25% for Lima."[121] Furthermore, throughout the country of Peru, "excess deaths decreased 14-fold over four months" leading up to December 1, 2020, "after which deaths then increased 13-fold when [ivermectin] use was restricted under a new president."[122]

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116 Juan J. Chamie-Quintero et al., *Ivermectin for COVID-19 in Peru: 14-fold reduction in nationwide excess deaths, p < 0.002 for effect by state, then 13-fold increase after ivermectin use restricted* (Mar. 2021), *available at* https://osf.io/9egh4/ (last visited Oct. 14, 2021); *see also* Santin, *supra*, at 3–4 (discussing the Peruvian data); Kory, *supra*, at 311–13 (same).

117 Chamie-Quintero, *supra*, at 2.

118 Santin, *supra*, at 3.

119 Chamie-Quintero, *supra*, at 2.

120 *Id.*

121 *Id.*

122 *Id.*

Ivermectin for COVID-19 in Peru: 14-fold reduction in nationwide excess deaths, p=.002 for effect by state, then 13-fold increase after ivermectin use restricted

Juan J. Chamie-Quintero,[a] Jennifer A. Hibberd,[b] David E Scheim[c]

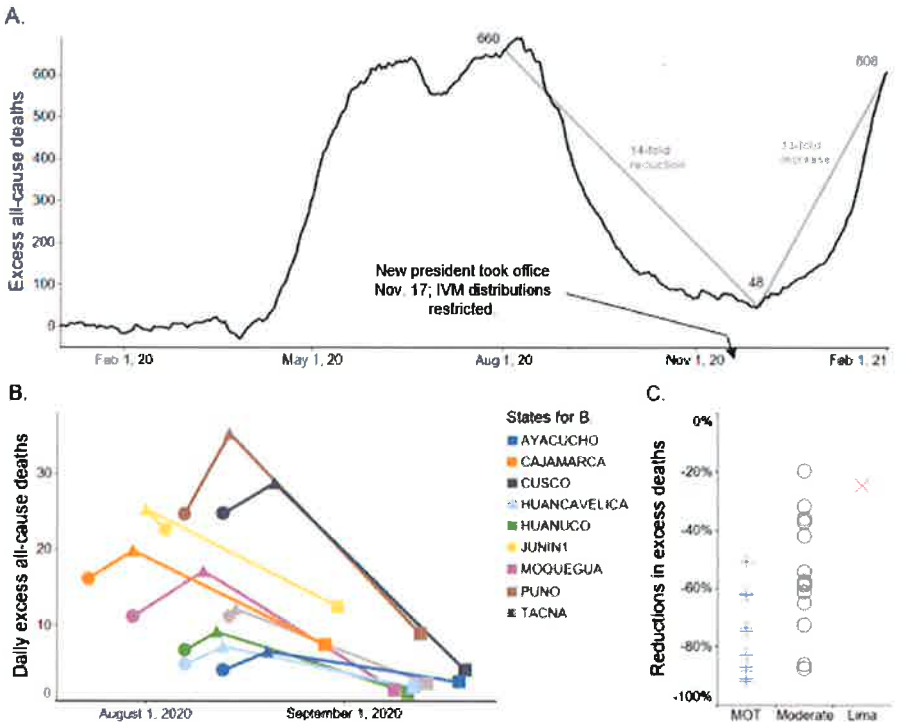

Figure 1. A) **Excess all-cause deaths (all ages), national population of Peru.** These decreased 14-fold August 1 through December 1, 2020; then, after IVM use was restricted, increased 13-fold through February 1. All y values are 7-day moving averages; for B,C, ages ≥ 60. Data are from Peru's National Death Information System (SINADEF).[12] B) Drops in excess deaths for all states of operation *MOT*, an army-led program of mass IVM distributions, but Pasco, which had them on 3 dates. ● *MOT* start date; ▲ peak deaths; ■ day of peak deaths + 30 days. Junin also distributed IVM 13 days before *MOT* start. C) Reductions in excess deaths at +30 days after peak deaths for the 25 states by extent of IVM distributions: maximal-*MOT* (+), mean -74%; moderate-local distributions (○), mean -53%; and minimal-Lima (x), -25%. These reductions for the 25 states correlated with extent of IVM distributions with Kendall τ_b p=0.002.

"Potential confounding factors, including lockdowns and herd immunity, were ruled out using Google community mobility data, seropositivity rates, population densities and geographic distributions of SARS-CoV-2 genetic variations."[123] While these figures do not prove causation, they demonstrate a strong correlation between ivermectin use and mortality reductions.

Moving from Peru to India, the government in the State of Uttar Pradesh—a jurisdiction with a population of more than 200 million—"introduced a large-scale 'prophylactic and therapeutic' use of [i]vermectin" that enabled it "to maintain a lower fatality and

123 Santin, *supra*, at 4.

positivity rate as compared to other states" in India.[124] As one state official explained, "Uttar Pradesh was the first state in [India] to introduce large-scale prophylactic and therapeutic use of Ivermectin."[125] The state's health department introduced ivermectin "as prophylaxis for close contacts of [COVID-19] patients" and "health workers," "as well as for the treatment of the patients themselves."[126] "Despite being [India's] state with the largest population base and a high population density," that state official added, Uttar Pradesh has "maintained a relatively low positivity rate and cases per million of population."[127] Although these statements from the Uttar Pradesh government do not prove ivermectin's effectiveness, they are informative and worthy of some consideration.

ii. U.S. Public Health Agencies on Ivermectin

Many public health agencies in the United States have now addressed the topic of ivermectin and COVID-19. The NIH has adopted a neutral position, saying that "[t]here is insufficient evidence . . . to recommend either for or against the use of ivermectin for the treatment of COVID-19."[128] This position, which the NIH adopted in January 2021, overrode its prior stance of "recommend[ing] against the use of ivermectin for the treatment" of COVID-19.[129] The reason for the change, the NIH recognized, was that "several randomized trials and retrospective cohort studies of ivermectin use in patients with COVID-19 have been published in peer-reviewed journals."[130] And some of those studies reported positive outcomes, including "shorter time to resolution of disease manifestations that were attributed to COVID-19, greater reduction in inflammatory marker levels, shorter time to viral clearance, [and] lower mortality rates in patients who received ivermectin than in patients who received comparator drugs or placebo."[131] The NIH nevertheless decided not to recommend the use of ivermectin for COVID-19 because other studies suggest "no benefits" and the NIH thought that the available studies

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124 Maulshree Seth, *Uttar Pradesh government says early use of Ivermectin helped to keep positivity, deaths low*, The Indian Express (May 12, 2021), *available at* https://indianexpress.com/article/cities/lucknow/uttar-pradesh-government-says-ivermectin-helped-to-keep-deaths-low-7311786/ (last visited Oct. 14, 2021), and https://www.msn.com/en-in/news/other/uttar-pradesh-government-says-early-use-of-ivermectin-helped-to-keep-positivity-deaths-low/ar-BB1gDp5U (last visited Oct. 14, 2021).

125 *Id.*

126 *Id.*

127 *Id.*

128 NIH, COVID-19 and Ivermectin, *supra*.

129 Yagisawa, *supra*, at 65.

130 NIH, COVID-19 and Ivermectin, *supra*.

131 *Id.*

generally suffered from "methodological limitations."[132] By making a neutral recommendation, the NIH—which is continuing to collaborate on at least one study investigating ivermectin as a treatment for "mild to moderate COVID-19"[133]—clearly signaled that physicians should use their discretion in deciding whether to treat COVID-19 patients with ivermectin.

Ignoring the NIH's official position, officials within its agencies have sent contradictory messages. On August 29, 2021, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID) within the NIH, went on CNN and announced that "there is no clinical evidence" that ivermectin works for the prevention or treatment of COVID-19.[134] Expanding on that point, he reiterated that "there is no evidence whatsoever" that it works.[135] Yet this definitive claim directly contradicts the NIH's recognition that "several randomized trials . . . published in peer-reviewed journals" have reported data indicating that ivermectin is effective as a COVID-19 treatment.[136]

The FDA has similarly charted a course of confusion. In March 2021, the FDA posted a webpage entitled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19."[137] Although the FDA's concern was stories of some people using the animal form of ivermectin or excessive doses of the human form, the title broadly condemned any use of ivermectin in connection with COVID-19. Yet there was no basis for its sweeping condemnation. Indeed, the FDA itself acknowledged on that very webpage (and continued to do so until the page changed on September 3, 2021) that the agency had *not* even "reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19."[138] But without reviewing the available data, which had long

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132 *Id.*

133 U.S. National Library of Medicine, ACTIV-6: COVID-19 Study of Repurposed Medications, https://clinicaltrials.gov/ct2/show/NCT04885530?term=activ-6&draw=2&rank=1 (last visited Oct. 14, 2021).

134 CNN Health, *'Don't do it': Dr. Fauci warns against taking Ivermectin to fight Covid-19* (Aug. 29, 2021), https://edition.cnn.com/videos/health/2021/08/29/dr-anthony-fauci-ivermectin-covid-19-sotu-vpx.cnn (last visited Oct. 14, 2021).

135 *Id.*

136 NIH, COVID-19 and Ivermectin, *supra*.

137 U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (archived Mar. 5, 2021), https://web.archive.org/web/20210305163946/https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021)").

138 *Id.*; *see also* U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (archived Sept. 2, 2021), https://web.archive.org/web/20210902231921/https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Sept. 2, 2021)").

since been available and accumulating, it is unclear what basis the FDA had for denouncing ivermectin as a treatment or prophylaxis for COVID-19.

On that same webpage, the FDA also declared that "[i]vermectin is not an anti-viral (a drug for treating viruses)."[139] It did so while another one of its webpages[140] simultaneously cited a study in *Antiviral Research* that identified ivermectin as a medicine "previously shown to have *broad-spectrum anti-viral activity*."[141] It is telling that the FDA deleted the line about ivermectin not being "anti-viral" when it amended the first webpage on September 3, 2021.[142]

The FDA has additionally assailed ivermectin's safety by suggesting, though not outright stating, that even a proper dose of human ivermectin might be dangerous when used to treat COVID-19. For example, the FDA announced that "[t]aking a drug for an unapproved use can be very dangerous" and "[t]his is true of ivermectin."[143] Yet this ignores the fact that, as discussed above, doctors routinely prescribe medicines for off-label use and that ivermectin is a particularly well-tolerated medicine with an established safety record. Moreover, it is inconsistent for the FDA to imply that ivermectin is dangerous when used to treat COVID-19 while the agency continues to approve remdesivir[144] despite its spottier safety record, as discussed above.

The FDA has also called into question ivermectin's potential effectiveness. When updating the "Why You Should Not Use Ivermectin" webpage on September 3, 2021, the FDA added this entry: "Currently available data do not show ivermectin is effective against COVID-19."[145] But this claim fails to recognize that several RCTs and at least one meta-analysis suggest that ivermectin is effective against COVID-19.

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139 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

140 U.S. Food and Drug Administration, FAQ: COVID-19 and Ivermectin Intended for Animals (Sept. 3, 2021), https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals (last visited Oct. 14, 2021).

141 Caly, *supra*, at 1 (emphasis added).

142 U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (updated Sept. 3, 2021), https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Sept. 3, 2021)").

143 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

144 U.S. Food and Drug Administration, FDA Approves First Treatment for COVID-19 (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19 (last visited Oct. 14, 2021).

145 FDA, Why You Should Not Use Ivermectin (Sept. 3 2021), *supra*.

Moreover, a review of the studies on remdesivir makes it difficult to understand why the FDA would condemn the data supporting ivermectin. The NIH reports only five studies testing remdesivir's efficacy against COVID-19.[146] Three of those five studies show *no benefit* from remdesivir, with the largest of those concluding that remdesivir "did not decrease in-hospital mortality in hospitalized patients."[147] Even the two remaining studies are far from compelling. One found that "[h]ospitalized patients . . . who received 5 days of [remdesivir] had better outcomes," but the difference "was of uncertain clinical importance."[148] And while the other study indicated that remdesivir "reduced time to clinical recovery" for "patients with severe COVID-19," it also found "[n]o observed benefit . . . in patients with mild or moderate COVID-19" and "[n]o statistically significant difference in mortality."[149] Beyond that, in September 2021, the Lancet published the results of a large RCT (the DisCoVeRy trial) that found "[n]o clinical benefit . . . from the use of remdesivir in patients who were admitted to hospital for COVID-19, were symptomatic for more than 7 days, and required oxygen support."[150] The data on ivermectin thus appears at least as strong as the data on remdesivir.

The FDA's most controversial statement on ivermectin came on August 21, 2021, when it posted a link on Twitter to its "Why You Should Not Use Ivermectin" webpage with this message: "You are not a horse. You are not a cow. Seriously, y'all. Stop it."[151]

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146 National Institutes of Health, Remdesivir: Selected Clinical Data, https://www.covid19treatmentguidelines.nih.gov/tables/table-2a/ (last visited Oct. 14, 2021).

147 *Id.*

148 *Id.*

149 *Id.*

150 Florence Ader et al., *Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial*, The Lancet, at 1 (Sept. 14, 2021), *available at* https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900485-0 (last visited Oct. 14, 2021).

151 U.S. FDA, Twitter, https://twitter.com/us_fda/status/1429050070243192839 (last visited Oct. 14, 2021).

This message is troubling not only because it makes light of a serious matter but also because it inaccurately implies that ivermectin is only for horses or cows.

Despite its attempts to impugn ivermectin, the FDA appears to recognize that doctors may prescribe it for COVID-19. On September 3, 2021, a change in its website makes this clear. The "Why You Should Not Use Ivermectin" webpage originally said that "[i]f you have a prescription for ivermectin for an FDA-approved use, get it from a legitimate source and take it exactly as prescribed."[152] That same sentence now omits the limitation on prescriptions to FDA-approved uses. It says that "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed."[153] This change implicitly acknowledges that ivermectin may be prescribed off-label for COVID-19.

The CDC has followed in the FDA's footsteps of implying that ivermectin is unsafe. On August 26, 2021, the CDC issued an official advisory entitled "Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19."[154] Like the FDA, the CDC's

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152 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

153 FDA, Why You Should Not Use Ivermectin (Sept. 3, 2021), *supra*.

154 Centers for Disease Control and Prevention, *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat*

sweeping title implies that severe illnesses are arising from the prescribed use of human ivermectin to combat COVID-19, but it supplies no data to indicate that human ivermectin in appropriate doses is harming anyone. On the contrary, the CDC's advisory acknowledges that the actual concerns arise from the "use of veterinary products not meant for human consumption" and that the reported "[a]dverse effects [are] associated with ivermectin misuse and overdose."[155] The CDC's instructions to the public confirm that its concerns arise from the improper use of ivermectin creams or animal formulas: "Do not swallow ivermectin products that should be used on skin (e.g., lotions and creams) or are not meant for human use, such as veterinary ivermectin products."[156]

None of this undermines the use of human ivermectin in proper doses for the treatment or prevention of COVID-19. If anything, the reported uptick in people resorting to animal ivermectin simply reinforces that COVID-19 patients should be encouraged to discuss human ivermectin with their healthcare providers and that those providers should be allowed to consider the available data with their patients. That would be more beneficial for public health than attempting to obscure the demonstrated safety profile of ivermectin.

The media has added to the confusion and misinformation. On August 30, 2021, the New York Times published an article about ivermectin stating that "Mississippi's health department said earlier this month that *70 percent* of recent calls to the state poison control center had come from people who ingested ivermectin from livestock supply stores."[157] Yet two weeks later, on September 13, 2021, the Times amended its story by deleting that sentence and adding this note after the article: "An earlier version of this article misstated the percentage of recent calls to the Mississippi poison control center related to ivermectin. It was 2 percent, not 70 percent."[158]

Similarly, on September 3, 2021, Rolling Stone published a story entitled "Gunshot Victims Left Waiting as Horse Dewormer Overdoses Overwhelm Oklahoma Hospitals,

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COVID-19, Health Advisory, at 1 (Aug. 26, 2021), *available at* https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf (last visited Oct. 14, 2021).

155 *Id.*

156 *Id.* at 3.

157 Emma Goldberg, *Demand Surges for Deworming Drug for Covid, Despite No Evidence It Works*, New York Times (Aug. 30, 2021), *available at* https://web.archive.org/web/20210830091038/https://www.nytimes.com/2021/08/30/health/covid-ivermectin-prescriptions.html (last visited Oct. 14, 2021) (emphasis added).

158 Emma Goldberg, *Demand Surges for Deworming Drug for Covid, Despite No Evidence It Works*, New York Times (amended Sept. 28, 2021), *available at* https://www.nytimes.com/2021/08/30/health/covid-ivermectin-prescriptions.html (last visited Oct. 14, 2021).

Doctor Says."[159] Soon thereafter, one the hospitals where this doctor supposedly works denied that claim, and "the doctor [did] not respond[] to requests for further comment."[160] Rather than delete the article or substantially rewrite it, Rolling Stone left the article largely unchanged and amended the title to say: "One Hospital Denies Oklahoma Doctor's Story of Ivermectin Overdoses Causing ER Delays for Gunshot Victims."[161] In addition, the magazine added an "update" message stating, among other things, that "[o]ne hospital has denied [the doctor's] claim that ivermectin overdoses are causing emergency room backlogs and delays in medical care in rural Oklahoma, and Rolling Stone has been unable to independently verify any such cases as of the time of this update."[162] In other words, the publication allowed a story based on a discredited and nonresponsive source to remain available to the public. It is no wonder that some people are unsure what to believe about ivermectin.

iii. Foreign Public Health Agencies on Ivermectin

Looking abroad, in March 2021, the WHO "recommend[ed] not to use ivermectin in patients with COVID-19 except in the context of a clinical trial."[163] The basis for this recommendation rested not on proof that ivermectin is ineffective, but on the WHO's belief that the existing studies were of too low quality to support any conclusive determinations.[164] Notably, though, while the WHO questioned the quality of the evidence, its analysis determined, based on data from 1,419 patients in seven studies, that patients treated with ivermectin had a 14 per 1,000 chance of death while patients in the control groups had a 70 per 1,000 chance of death.[165] Also, the WHO considered only

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159 Peter Wade, *Gunshot Victims Left Waiting as Horse Dewormer Overdoses Overwhelm Oklahoma Hospitals, Doctor Says*, Rolling Stone (Sept. 3, 2021), *available at* https://web.archive.org/web/20210903231939/https://www.rollingstone.com/politics/politics-news/gunshot-victims-horse-dewormer-ivermectin-oklahoma-hospitals-covid-1220608/ (last visited Oct. 14, 2021).

160 Peter Wade, *One Hospital Denies Oklahoma Doctor's Story of Ivermectin Overdoses Causing ER Delays for Gunshot Victims*, Rolling Stone (amended Sept. 5, 2021), *available at* https://www.rollingstone.com/politics/politics-news/gunshot-victims-horse-dewormer-ivermectin-oklahoma-hospitals-covid-1220608/ (last visited Oct. 14, 2021).

161 *Id.*

162 *Id.*

163 World Health Organization, Therapeutics and COVID-19: Living Guideline, at 20 (July 6, 2021), *available at* https://files.magicapp.org/guideline/a6e3f83e-bff5-481c-90ab-130aa86bbe83/published_guideline_5486-6_1.pdf (last visited Oct. 14, 2021) (hereinafter, "WHO COVID-19 Guidelines").

164 *Id.*

165 *Id.* at 23.

ivermectin's effectiveness as a COVID-19 treatment and did not assess its potential as a prophylaxis.[166]

Public health authorities in other countries have declined to follow the WHO's guidance. Most importantly, the NIH continues to embrace its neutral recommendation on ivermectin. Also, in May 2021, the State of Goa in India announced, through its health minister Vishwajit Rane, that "it would give [ivermectin] to all its adult residents" in its efforts to combat COVID-19.[167] Likewise, as discussed above, India's Uttar Pradesh continues to distribute ivermectin to people diagnosed with COVID-19. And El Salvador's Ministry of Public Health has included ivermectin as part of its recommendations for early COVID-19 treatment via home patient kit.[168] We did not conduct an exhaustive search on other countries' practices, so this list is simply intended to be illustrative.

iv. Professional Associations and Physicians on Ivermectin

Professional associations, both here in the United States and abroad, have adopted conflicting positions on ivermectin and COVID-19. The American Medical Association (AMA), American Pharmacists Association (APhA), and American Society of Health-System Pharmacists (ASHP) have issued a statement that "strongly oppose[s] the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial."[169] But this statement relies solely on the FDA's and CDC's statements. Consider the AMA, APhA, and ASHP's claim that "[u]se of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients."[170] Their only support for that alarming statement is the CDC Health Alert discussed above.[171] But as we explained, that CDC advisory gave no indication that any severe adverse effects are occurring from the use of human ivermectin in appropriate doses.

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166 *Id.* at 18.

167 Siladitya Ray, *Indian State Will Offer Ivermectin To Entire Adult Population — Even As WHO Warns Against Its Use As Covid-19 Treatment*, Forbes (May 11, 2021), *available at* https://www.forbes.com/sites/siladityaray/2021/05/11/indian-state-will-offer-ivermectin-to-entire-adult-population---even-as-who-warns-against-its-use-as-covid-19-treatment/?sh=3d45adce6d9f (last visited Oct. 14, 2021).

168 *El Salvador Minister of Public Health Includes Ivermectin as COVID-19 Pandemic Continues*, TrialSite News (Aug. 26, 2021), *available at* https://trialsitenews.com/el-salvador-minister-of-public-health-includes-ivermectin-as-covid-19-pandemic-continues/ (last visited Oct. 14, 2021).

169 American Medical Association, AMA, APhA, ASHP statement on ending use of ivermectin to treat COVID-19 (Sept. 1, 2021), *available at* https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19 (last visited Oct. 14, 2021) (hereinafter, "AMA, APhA, and ASHP Statement on Ivermectin").

170 *Id.*

171 *Id.*

Those groups' opposition to ivermectin also conflicts with their otherwise steadfast support for healthcare providers' rights to prescribe medicines for off-label use. They call for ivermectin's ban because the FDA has not approved it "to prevent or treat COVID-19" and some public-health agencies have found "insufficient evidence" to support its use.[172] But just last year, these same professional associations, when discussing prescriptions for hydroxychloroquine to treat COVID-19, affirmed that "[n]ovel off-label use of FDA-approved medications is a matter for the physician's or other prescriber's professional judgment."[173] Moreover, the AMA elsewhere recognizes "its strong support for the autonomous clinical decision-making authority of . . . physician[s]" to "lawfully use an FDA approved drug product . . . for an off-label indication when such use is based upon sound scientific evidence."[174] In their recent ivermectin statement, however, the AMA, APhA, and ASHP ignore that some sound scientific evidence, including meta-analyses of RCTs, supports the use of ivermectin for COVID-19.

The AMA, APhA, and ASHP mentioned the statement of Merck—the original patentholder on ivermectin—as an additional basis for their position.[175] Yet that does not provide persuasive support for their opposition to ivermectin. Merck's February 2021 statement expressed its view that there is "[n]o meaningful evidence for . . . clinical efficacy in patients with COVID-19,"[176] but this simply ignores the RCTs demonstrating ivermectin's efficacy. Merck then claimed that there is "[a] concerning lack of safety data in the majority of studies."[177] While worded vaguely, this statement, when read carefully, says next to nothing. It simply acknowledges that many of the studies it references did not track safety data. It is not saying, though it might be implying, that the studies showed the medicine to be dangerous. But Merck, of all sources, knows that ivermectin is exceedingly safe, so the absence of safety data in recent studies should not be concerning to the company.

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172 *Id.*

173 American Medical Association, Joint statement on ordering, prescribing or dispensing COVID-19 medications (Apr. 17, 2020), *available at* https://www.ama-assn.org/delivering-care/public-health/joint-statement-ordering-prescribing-or-dispensing-covid-19 (last visited Oct. 14, 2021).

174 American Medical Association, Patient Access to Treatments Prescribed by Their Physicians, https://policysearch.ama-assn.org/policyfinder/detail/Patient%20Access%20to%20Treatments%20Prescribed%20by%20Their%20Physicians%20H-120.988%20%20?uri=%2FAMADoc%2FHOD.xml-0-201.xml (last visited Oct. 14, 2021).

175 AMA, APhA, and ASHP Statement on Ivermectin, *supra*.

176 Merck, Merck Statement on Ivermectin use During the COVID-19 Pandemic (Feb. 4, 2021), https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/ (last visited Oct. 14, 2021).

177 *Id.*

Why would ivermectin's original patentholder go out of its way to question this medicine by creating the impression that it might not be safe? There are at least two plausible reasons. First, ivermectin is no longer under patent, so Merck does not profit from it anymore. That likely explains why Merck declined to "conduct[] clinical trials" on ivermectin and COVID-19 when given the chance.[178] Second, Merck has a significant financial interest in the medical profession rejecting ivermectin as an early treatment for COVID-19. "[T]he U.S. government has agreed to pay [Merck] about $1.2 billion for 1.7 million courses of its experimental COVID-19 treatment, if it is proven to work in an ongoing large trial and authorized by U.S. regulators."[179] That treatment, known as "molnupiravir, aims to stop COVID-19 from progressing and can be given early in the course of the disease."[180] On October 1, 2021, Merck announced that preliminary studies indicate that molnupiravir "reduced hospitalizations and deaths by half,"[181] and that same day its stock price "jumped as much as 12.3%."[182] Thus, if low-cost ivermectin works better than—or even the same as—molnupiravir, that could cost Merck billions of dollars.

While one side of the "professional associations" ledger includes the AMA, APhA, and ASHP (with Merck's backing), other associations disagree with their stance. In particular, the Association of American Physicians and Surgeons (AAPS)—a long-established group that has represented doctors in all specialties since 1943—has raised questions concerning those associations' "startling and unprecedented position that American physicians should immediately stop prescribing, and pharmacists should stop honoring their prescriptions for ivermectin for COVID-19 patients."[183] The AAPS pointed "out that many physicians disagree with the AMA, writing around 88,000 ivermectin

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178 Yagisawa, *supra*, at 61.

179 *U.S. signs $1.2 bln deal for 1.7 mln courses of Merck's experimental COVID-19 drug*, Reuters (Jun. 9, 2021), *available at* https://www.reuters.com/business/healthcare-pharmaceuticals/merck-says-us-govt-buy-about-17-mln-courses-cos-covid-19-drug-2021-06-09/ (last visited Oct. 14, 2021).

180 *Id.*

181 Matthew Perrone, *Merck says COVID-19 pill cuts risk of death, hospitalization*, Associated Press (Oct. 1, 2021), *available at* https://apnews.com/article/merck-says-experimental-covid-pill-cuts-worst-effects-a9a2245fdcee324f6bbd776a0fffcc60 (last visited Oct. 14, 2021).

182 Lewis Krauskopf & Manojna Maddipatla, *Merck COVID-19 pill success slams Moderna shares, shakes up healthcare sector*, Reuters (Oct. 1, 2021), *available at* https://www.reuters.com/business/healthcare-pharmaceuticals/merck-covid-19-pill-success-slams-moderna-shares-shakes-up-healthcare-sector-2021-10-01/ (last visited Oct. 14, 2021).

183 Association of American Physicians and Surgeons, AAPS Challenges the AMA on Efforts to Suppress Ivermectin Use in COVID (Sept. 4, 2021), *available at* https://aapsonline.org/aaps-challenges-the-ama-on-efforts-to-suppress-ivermectin-use-in-covid/ (last visited Oct. 14, 2021).

prescriptions per week."[184] The AAPS has thus publicly resisted these groups' call to "stop[] the off-label use of long-approved drugs."[185]

In addition, the Tokyo Metropolitan Medical Association, as explained by its chairman Haruo Ozaki, recommended the use of ivermectin for COVID-19 patients in February 2021.[186] That organization emphasized that ivermectin should be administered to people diagnosed with COVID-19 because, among other reasons, it has been effective when used in other countries.[187] Other doctors' groups similarly advocate for ivermectin as a staple of early COVID-19 treatment. The Front Line COVID-19 Critical Care Alliance has been an outspoken supporter. Its organization "regard[s] ivermectin as a core medication in the prevention and treatment of COVID-19,"[188] and it includes a five-day course of ivermectin as part of its COVID-19 early treatment protocol.[189] Also, the British Ivermectin Recommendation Development Group (BIRD) is a UK-based association of "clinicians, health researchers[,] and patient representatives from all around the world" that collectively "advocate[s] for the use of ivermectin" against COVID-19.[190]

In summary, the evidence discussed above shows (1) that ivermectin has demonstrated some effectiveness in preventing and treating COVID-19 and (2) that its side effects are primarily minor and transient. Thus, the UCA does not preclude physicians from considering ivermectin for the prevention or treatment of COVID-19.

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184 *Id.*

185 *Id.*

186 Tokyo Metropolitan Medical Association recommends ivermectin administration to prevent aggravation, Nikkei (Feb. 9, 2021), https://www.nikkei.com/article/DGXZQOFB25AAL0V20C21A1000000/ (last visited Oct. 14, 2021).

187 *Id.*

188 Front Line COVID-19 Critical Care Alliance, Ivermectin in COVID-19, https://covid19criticalcare.com/ivermectin-in-covid-19/ (last visited Oct. 14, 2021).

189 Front Line COVID-19 Critical Care Alliance, Prevention & Treatment Protocols for COVID-19, https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Alliance-I-MASKplus-Protocol-ENGLISH.pdf (last visited Oct. 14, 2021).

190 British Ivermectin Recommendation Development Group, Who are the BIRD Group, https://bird-group.org/who-are-bird/ (last visited Oct. 14, 2021).

4. Hydroxychloroquine

A. History of Hydroxychloroquine

Hydroxychloroquine, a less toxic derivative of a medicine named chloroquine, was first developed in 1946[191] and approved by the FDA in 1955.[192] Since that time, hydroxychloroquine has been widely used as a prophylaxis and treatment for malaria.[193] It has also "prove[n] to be effective in a number of autoimmune diseases," including systemic lupus erythematosus,[194] primary Sjögren's syndrome, and rheumatoid arthritis, and for those uses, it is often taken daily for years at a time.[195] Hydroxychloroquine's success against these autoimmune diseases "is linked to its anti-inflammatory and immunomodulatory effects."[196] Because of its versatility and efficacy, "[m]illions of hydroxychloroquine doses are prescribed annually."[197] In just the year 2019, hydroxychloroquine was prescribed over 5.4 million times in the United States alone.[198]

In 2004, long before the COVID-19 pandemic began, a lab study revealed that chloroquine is "an effective inhibitor of the replication of the severe acute respiratory syndrome coronavirus (SARS-CoV) in vitro" and thus that it should "be considered for immediate use in the prevention and treatment of SARS-CoV infections."[199] The following

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191 National Institutes of Health, COVID-19 Treatment Guidelines: Chloroquine or Hydroxychloroquine and/or Azithromycin, https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/chloroquine-or-hydroxychloroquine-and-or-azithromycin/ (last visited Oct. 14, 2021) (hereinafter, "NIH, COVID-19 and Hydroxychloroquine").

192 Georgi Fram et al., *Cardiac Complications Attributed to Hydroxychloroquine: A Systematic Review of the Literature Pre-COVID-19*, 17 Current Cardiology Reviews 389, 389 (2021), *available at* https://www.eurekaselect.com/186876/article (last visited Oct. 14, 2021).

193 *Id.*

194 Claudio Ponticelli & Gabriella Moroni, *Hydroxychloroquine in systemic lupus erythematosus (SLE)*, 16 Expert Opinion on Drug Safety 411, 411 (2017), *available at* https://www.tandfonline.com/doi/full/10.1080/14740338.2017.1269168?scroll=top&needAccess=true (last visited Oct. 14, 2021).

195 Eliise Laura Nirk et al., *Hydroxychloroquine in rheumatic autoimmune disorders and beyond*, EMBO Molecular Medicine, at 1 (Aug. 2020), *available at* https://www.embopress.org/doi/epdf/10.15252/emmm.202012476 (last visited Oct. 14, 2021).

196 *Id.*

197 Fram, *supra*, at 389.

198 ClinCalc, Hydroxychloroquine Drug Usage Statistics, United States, 2013–2019, https://clincalc.com/DrugStats/Drugs/Hydroxychloroquine (last visited Oct. 14, 2021).

199 Els Keyaerts et al., *In vitro inhibition of severe acute respiratory syndrome coronavirus by chloroquine*, 323 Biochemical and Biophysical Research Communications 264, 264 (2004), *available at* https://www.sciencedirect.com/science/article/pii/S0006291X0401839X (last visited Oct. 14, 2021).

year, another paper explained that "chloroquine has strong antiviral effects on SARS-CoV infection" and "is effective in preventing the spread of SARS[-]CoV in cell culture."[200]

It is widely recognized in the medical community that hydroxychloroquine is generally safe, so safe in fact that it may be prescribed to pregnant women[201] and "children of all ages."[202] During the beginning of the pandemic, the FDA Commissioner stated that hydroxychloroquine has "a well-established safety profile" for malaria, lupus, and rheumatoid arthritis.[203] According to the CDC, hydroxychloroquine's "most common adverse reactions reported" are minor issues such as "stomach pain, nausea, vomiting, . . . headache," and "itching."[204] While the CDC recognizes that high doses, "such as those used to treat rheumatoid arthritis, have been associated with retinopathy," a serious eye condition, that side effect is "extremely unlikely" when hydroxychloroquine is used in short durations with moderate doses.[205] Notably, the CDC's guidance on hydroxychloroquine does not mention any concerns about cardiac disorders stemming from the drug.

B. Hydroxychloroquine and COVID-19

At the outset of the pandemic, researchers found—consistent with the prior studies demonstrating chloroquine's efficacy against SARS-CoV—that hydroxychloroquine "can efficiently inhibit SARS-CoV-2 infection in vitro."[206] These COVID-19 studies specifically

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200 Martin J. Vincent et al., *Chloroquine is a potent inhibitor of SARS coronavirus infection and spread*, Virology Journal, at 1 (Aug. 2005), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/pdf/1743-422X-2-69.pdf (last visited Oct. 14, 2021).

201 Ponticelli & Moroni, *supra*, at 411; *see also* Ewa Haładyj et al., *Antimalarials - are they effective and safe in rheumatic diseases?*. 56 Reumatologia 164, 171–72 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052376/pdf/RU-56-33240.pdf (last visited Oct. 14, 2021) (noting that hydroxychloroquine "can be continued in the treatment of rheumatic diseases during pregnancy and lactation").

202 Centers for Disease Control and Prevention, Medicines for the Prevention of Malaria While Traveling Hydroxychloroquine (Plaquenil™), https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf (last visited Oct. 14, 2021) (hereinafter, "CDC, Malaria Travel").

203 U.S. Food & Drug Administration, Bringing a Cancer Doctor's Perspective to FDA's Response to the COVID-19 Pandemic (Mar. 29, 2020), https://www.fda.gov/news-events/fda-voices/bringing-cancer-doctors-perspective-fdas-response-covid-19-pandemic (last visited Oct. 14, 2021) (hereinafter, "FDA, Bringing Perspective").

204 CDC, Malaria Travel, *supra*.

205 Centers for Disease Control and Prevention, Yellow Book, Chapter 4: Travel-Related Infectious Diseases – Malaria (2020), *available at* https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria#1939 (last visited Oct. 14, 2021).

206 Jia Liu et al., *Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro*, Cell Discovery, at 4 (2020), *available at* https://www.nature.com/articles/s41421-020-0156-0.pdf (last visited Oct. 14, 2021).

showed that hydroxychloroquine "can inhibit [SARS-CoV-2] virus entry, transmission[,] and replication."[207] In addition to this "antiviral activity," hydroxychloroquine also has "anti-inflammatory properties" that help regulate "pro inflammatory cytokines."[208] These characteristics—both the antiviral properties and the anti-inflammatory activity—are important countermeasures against COVID-19.

i. Hydroxychloroquine Studies and Meta-analyses

Many large observational studies suggest that hydroxychloroquine significantly reduces the risk of hospitalization and death when administered to outpatients—particularly high-risk outpatients—as part of early COVID-19 treatment. For example, the Mokhtari study "was a multicenter, population-based national retrospective-cohort investigation of 28,759 adults with mild COVID-19 seen . . . between March and September 2020 throughout Iran."[209] The data showed that "[t]he odds of hospitalization . . . reduced by 38%" and the chance of death decreased by 73% for those who took hydroxychloroquine.[210] Critically, those "effects were maintained after adjusting for age, comorbidities, and diagnostic modality," and "[n]o serious [hydroxychloroquine]-related adverse drug reactions were reported."[211]

In the same vein, the recently published Million study evaluated 10,429 "adult outpatients" in France infected with SARS-CoV-2 who were "treated early" with hydroxychloroquine plus azithromycin.[212] Only five deaths occurred among the 8,315 patients who received hydroxychloroquine plus azithromycin—a mere 0.6 per 1,000 patients—while 11 died among the 2,114 who received either no treatment or azithromycin alone—a much higher rate of 5.2 per 1,000 patients.[213] Based on these figures, the study's authors found that hydroxychloroquine "was associated with a lower risk of death, independently of age, sex[,] and epidemic period."[214] Million's team thus concluded that

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207 Jyoti Bajpai et al., *Hydroxychloroquine and COVID-19 - A narrative review*, 67 Indian Journal of Tuberculosis 147, 148 (Dec. 2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7836863/pdf/main.pdf (last visited Oct. 14, 2021).

208 *Id.*

209 Majid Mokhtari et al., *Clinical outcomes of patients with mild COVID-19 following treatment with hydroxychloroquine in an outpatient setting*, International Immunopharmacology, at 1 (Jul. 2021), *available at* https://www.sciencedirect.com/science/article/pii/S1567576921002721 (last visited Oct. 14, 2021).

210 *Id.*

211 *Id.*

212 Million, *supra*, at 1063.

213 *Id.* at 1066.

214 *Id.* at 1063.

"[e]arly ambulatory treatment of COVID-19" with hydroxychloroquine plus azithromycin "is associated with very low mortality" and it "improve[s] COVID-19 survival compared to other regimens."[215]

Another group of researchers assessed an elderly population living in a nursing home in the small European state of Andorra.[216] Their study included "100 COVID-19 confirmed cases" in the nursing home "from March 15 to June 5, 2020."[217] After evaluating the numbers, these researchers concluded that "[t]reatment with hydroxychloroquine and azithromycin was associated with lower mortality in these patients."[218] And "the multivariate logistic regression analysis identified hydroxychloroquine plus azithromycin treatment as an independent factor favoring survival compared with no treatment or other treatments."[219] The study also reinforced hydroxychloroquine's longstanding safety profile because "[c]ardiac monitoring was performed by electrocardiogram, and no rhythm changes were observed . . . in any patient."[220]

Added to all this, a preprint of another large observational study by Sulaiman supports the use of hydroxychloroquine as part of early COVID-19 treatment.[221] This "study took place in 238 ambulatory fever clinics in Saudi Arabia" during June 2020.[222] Of the 5,541 participating patients, 1,817 were given hydroxychloroquine, and 3,724 received only supportive care.[223] The researchers found that early hydroxychloroquine-based "therapy was associated with a lower hospital admission" of 9.4% compared to 16.6% for supportive care alone, which equated to a relative risk reduction of 43%. "Adjusting for age, gender, and major comorbid conditions, a multivariate logistic regression model" further confirmed the significant decrease in the hospitalization risk of

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215 *Id.*

216 Eva Heras et al., *COVID-19 mortality risk factors in older people in a long-term care center*, 12 European Geriatric Medicine 601, 601 (2021), *available at* https://link.springer.com/content/pdf/10.1007/s41999-020-00432-w.pdf (last visited Oct. 14, 2021).

217 *Id.*

218 *Id.*

219 *Id.* at 606.

220 *Id.* at 603.

221 Tarek Sulaiman et al., *The Effect of Early Hydroxychloroquine-based Therapy in COVID-19 Patients in Ambulatory Care Settings: A Nationwide Prospective Cohort Study*, Preprint, at 1 (2020), *available at* https://www.medrxiv.org/content/10.1101/2020.09.09.20184143v1.full.pdf (last visited Oct. 14, 2021).

222 *Id.*

223 *Id.*

patients who received hydroxychloroquine.[224] Regression analysis also demonstrated that hydroxychloroquine reduced the mortality risk by an odds ratio of .36, which equates to a threefold drop in deaths.[225] Other observational studies further suggest that hydroxychloroquine has value as an early COVID-19 treatment.[226]

We acknowledge that other studies and meta-analyses have concluded that hydroxychloroquine has little to no effect on COVID-19.[227] Yet those materials generally blur the important distinction between hydroxychloroquine's efficacy as an early treatment for mild COVID-19 in nonhospitalized patients and its efficacy as a late treatment for severe COVID-19 in hospitalized patients.[228] As explained above, COVID-19 in its early stages, which consists primarily of cold- and flu-like symptoms, is very different from severe COVID-19, which is a lower respiratory disease often accompanied by respiratory failure and multiple organ dysfunction. Thus, evidence about hydroxychloroquine's use "in inpatients[] is irrelevant with regard to the efficacy of [the drug] in early high-risk outpatient disease."[229] So even if hydroxychloroquine is not effective against severe COVID-19, that does not disprove its value as an early treatment against the disease.

The key, then, is to focus on data that assess hydroxychloroquine's effectiveness in early treatment. A prime example of that is a recently published meta-analysis that combined the Million, Mokhtari, and Sulaiman studies discussed above with two other

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224 *Id.*

225 *Id.* at 14.

226 *E.g.*, Andrew Ip et al., *Hydroxychloroquine in the treatment of outpatients with mildly symptomatic COVID-19: a multi-center observational study*, BMC Infectious Diseases (2021), *available at* https://bmcinfectdis.biomedcentral.com/track/pdf/10.1186/s12879-021-05773-w.pdf (concluding in a study of 1,274 outpatients with SARS-CoV-2 infection that "there was an association between exposure to hydroxychloroquine and a decreased rate of hospitalization from COVID-19"); Yi Su, *Efficacy of early hydroxychloroquine treatment in preventing COVID-19 pneumonia aggravation, the experience from Shanghai, China*, 14 BioScience Trends 408, 408 (2020), *available at* https://www.jstage.jst.go.jp/article/bst/14/6/14_2020.03340/_pdf/-char/en (last visited Oct. 14, 2021) (finding in a study of 616 individuals that "[t]he early use of hydroxychloroquine decreased the improvement time and the duration of COVID-19 detection in throat and stool swabs").

227 Tawanda Chivese et al., *Efficacy of chloroquine and hydroxychloroquine in treating COVID-19 infection: A meta-review of systematic reviews and an updated meta-analysis*, Travel Medicine and Infectious Disease, at 1 (Sept./Oct. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8273040/pdf/main.pdf (last visited Oct. 14, 2021) (concluding that hydroxychloroquine is "not effective in treating COVID-19").

228 *Id.* at 3 (noting that this meta-analysis considered studies of people with "confirmed COVID-19, regardless of . . . the severity of illness").

229 Harvey A. Risch, *Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately as Key to the Pandemic Crisis*, 189 American Journal of Epidemiology 1218, 1218 (Nov. 2020), *available at* https://academic.oup.com/aje/article/189/11/1218/5847586 (last visited Oct. 14, 2021).

outpatient studies.[230] Those five studies together included 32,124 total outpatients, and the analysis revealed that hydroxychloroquine is associated with a 69% reduction in mortality when used as an early COVID-19 treatment.[231] In addition, a few months ago, another team of researchers reviewed "nine reports of early treatment outcomes in COVID-19 nursing home patients."[232] Data from those studies revealed that "hydroxychloroquine-based multidrug regimens were associated with a statistically significant > 60% reduction in mortality."[233] And another scholar, Dr. Harvey A. Risch, Professor of Epidemiology at Yale School of Public Health, has published online a non-peer-reviewed meta-analysis of ten studies exploring hydroxychloroquine as an early COVID-19 treatment.[234] He concluded that for people receiving that treatment the odds ratio of hospitalization was .56 and the odds ratio of death was .25. In other words, his meta-analysis demonstrated that when hydroxychloroquine is administered as an early COVID-19 treatment, it can reduce the risk of death by 75%.

To be sure, these data derive from large-scale observational studies rather than RCTs, and we understand that RCTs are considered the gold standard in medicine. But for at least two reasons, we find these observational studies sufficient for our purposes. First, our role is not to set a standard for the practice of medicine. Rather, we must simply confirm whether reasonable medical evidence supports the use of hydroxychloroquine as an early COVID-19 treatment, and we determine that a collection of large-scale observational studies suffices for that purpose. Second, a seminal review of the scientific literature has revealed that "on average, there is little evidence for significant effect estimate differences between observational studies and RCTs, regardless of specific observational study design, heterogeneity, or inclusion of studies of pharmacological interventions."[235] There is thus no basis to cast aside the observational studies demonstrating hydroxychloroquine's efficacy as an early COVID-19 treatment.

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230 Million, *supra*, at 1070.

231 *Id.*

232 Paul E. Alexander et al., *Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents*, Medical Hypotheses, at 1 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8178530/pdf/main.pdf (last visited Oct. 14, 2021).

233 *Id.*

234 Harvey A. Risch, *Hydroxychloroquine in Early Treatment of High-Risk COVID-19 Outpatients: Efficacy and Safety Evidence*, at 11 (Jun. 17, 2021), *available at* https://earlycovidcare.org/wp-content/uploads/2021/09/Evidence-Brief-Risch-v6.pdf (last visited Oct. 14, 2021).

235 Andrew Anglemyer et al., *Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials*, Cochrane Database of Systematic Reviews, at 1 (2014), *available at* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000034.pub2/epdf/full (last visited Oct. 14, 2021).

We turn now to discuss the use of hydroxychloroquine as a prophylaxis, and although the data on that point seem to be smaller, there is some evidence suggesting that it might work for that purpose too. One study was a RCT of migrant workers quarantined in a large dormitory in Singapore, and it compared a group who used hydroxychloroquine as a prophylaxis to a group that received only vitamin C.[236] The hydroxychloroquine group included 432 people, and only 31 of them (7.2%) contracted COVID-19 with acute respiratory symptoms.[237] In contrast, 619 individuals were in the vitamin C group, and 69 of them (11.1%) developed COVID-19 with acute respiratory symptoms.[238] Thus, the researchers concluded that prophylaxis with hydroxychloroquine is "superior to oral vitamin C in reducing SARS-CoV-2 infection."[239] Additionally, an observational study of healthcare workers in Bulgaria found that out of 156 workers who used hydroxychloroquine as a prophylaxis, none of them presented with COVID-19 symptoms.[240] By contrast, in the group of 48 workers who did not take hydroxychloroquine, three of them developed a symptomatic case of COVID-19.[241] These results prompted the administrators at the Bulgarian Cardiac Institute to start a prophylactic strategy for their workers that "includes alternative months of [hydroxychloroquine] intake (200 mg daily) and months without therapy."[242] In addition to these studies, there are a few others, some of which suggest marginal benefits, and some of which suggest that there might not be any. We are not aware of any of these studies showing serious adverse effects from use of low-dose hydroxychloroquine as a COVID-19 prophylaxis.

We pause here to reiterate that it is not our role to resolve the debate on hydroxychloroquine's effectiveness, either as an early COVID-19 treatment or as a preventative measure. These are matters for individual healthcare providers to assess based on the available data in consultation with their patients. Our only point is that reasonable data support the use of hydroxychloroquine as an early COVID-19 treatment and as a prophylaxis, and in light of that, we cannot find clear and convincing evidence

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236 Raymond Chee Seong Seet et al., *Positive impact of oral hydroxychloroquine and povidone-iodine throat spray for COVID-19 prophylaxis: An open-label randomized trial*, 106 International Journal of Infectious Diseases 314, 314 (2021), *available at* https://www.ijidonline.com/action/showPdf?pii=S1201-9712%2821%2900345-3 (last visited Oct. 14, 2021).

237 *Id.* at 319.

238 *Id.*

239 *Id.* at 314.

240 Iana Simova et al., *Hydroxychloroquine for prophylaxis and treatment of COVID-19 in health-care workers*, New Microbes and New Infections, at 1 (Nov. 2020), *available at* https://www.sciencedirect.com/science/article/pii/S2052297520301657#! (last visited Oct. 14, 2021).

241 *Id.*

242 *Id.*

to file disciplinary actions against physicians who prescribe hydroxychloroquine for either of those purposes.

ii. Hydroxychloroquine, COVID-19, and Safety

During the pandemic, the FDA raised questions about hydroxychloroquine and adverse cardiac events.[243] These kinds of concerns prompted one group of scholars to conduct a systematic review of the hydroxychloroquine safety literature pre-COVID-19. Their review of the data indicated that people taking that medication in appropriate doses "are at very low risk of experiencing cardiac [adverse events], particularly with short term administration" of the drug.[244] The pre-COVID-19 data showed that heart issues occurred—albeit infrequently—only when patients took hydroxychloroquine in dangerously high doses or for many years on end.[245]

As to the increase of adverse cardiac events associated with COVID-19, the researchers questioned the prevalence of the problem by noting that several COVID-19 studies recorded "the use of [hydroxychloroquine] at variable doses without significant cardiac toxicity."[246] They also observed that COVID-19 itself often causes heart issues. As they explained, "[t]he underlying pathophysiology of SARS-CoV-2 contributes to cardiac complications in the population it infects, with estimates ranging from 20-40% incidence."[247] In particular, "[c]ardiac complications of cytokine storm have been well documented to involve fatal cardiac dysrhythmias and acute systolic heart failure."[248] These researchers thus concluded that "the reported increased arrhythmic events in the COVID-19 era appear to be more related with the direct inflammatory effect of the virus (myocarditis) or the concomitant administration of multiple drugs capable of prolonging QT intervals rather than to hydroxychloroquine itself."[249] They did not seem to think the medication itself had "change[d] after 70 years" of widespread use.[250]

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243 U.S. Food and Drug Administration, FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or (last visited Oct. 14, 2021).

244 Fram, *supra*, at 391.

245 *Id.* at 390–92.

246 *Id.* at 393.

247 *Id.* at 392.

248 *Id.* at 393.

249 *Id.* at 394.

250 *Id.*

Others echoed these views. Another group reviewed the relevant studies and observed that "[m]ost of the available and credible data suggest that [hydroxychloroquine] is a safe drug."[251] That includes the pre-COVID-19 data—in "decades of . . . use by rheumatologists, . . . cardiac toxicity was rarely ever seen"—as well as the COVID-19-related studies—for example, the RECOVERY trial found "no cardiotoxicity" by hydroxychloroquine.[252] Indeed, the RECOVERY trial "prove[d] that [hydroxychloroquine] did not increase cardiac complications in COVID-19 cases despite using 4 times higher dosage than that used by rheumatologists."[253] These authors also emphasized that "[m]ultiple mechanisms cause cardiac complications in patients with COVID-19 infection";[254] thus, the infection's propensity to cause "intrinsic cardiac abnormalities . . . is probably acting as a confounder."[255]

Still another set of researchers reevaluated hydroxychloroquine's safety during the pandemic. They conducted a "meta-analysis to compare the safety of [hydroxychloroquine] versus placebo" for any indication.[256] Although their "meta-analysis of RCTs found a significantly higher risk of skin pigmentation [issues] in [hydroxychloroquine] users versus placebo," they did not find any statistically significant increases in other adverse events, including "cardiac toxicity."[257]

In addition to these data tending to confirm hydroxychloroquine's safety when used in appropriate doses, a few other factors further lessen the cardiac concerns. For starters, one piece of key evidence contributing to the safety concerns surrounding hydroxychloroquine rested on admittedly fraudulent data. As discussed above, it was a study published in the Lancet on May 22, 2020.[258] That study claimed that hydroxychloroquine was "associated with . . . an increased frequency of ventricular

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251 Shivraj Padiyar & Debashish Danda, *Revisiting cardiac safety of hydroxychloroquine in rheumatological diseases during COVID-19 era: Facts and myths*, 8 European Journal of Rheumatology 100, 100 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8133889/pdf/ejr-8-2-100.pdf (last visited Oct. 14, 2021).

252 *Id.*

253 *Id.* at 102.

254 *Id.* at 102.

255 *Id.* at 100.

256 Khalid Eljaaly et al., *Hydroxychloroquine safety: A meta-analysis of randomized controlled trials*, Travel Medicine and Infectious Disease at 1 (Jul./Aug. 2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342171/ (last visited Oct. 14, 2021).

257 *Id.*

258 Mehra, *supra*.

arrhythmias when used for treatment of COVID-19."[259] That supposed finding was so startling that "major drug trials" involving hydroxychloroquine "were immediately halted";[260] the WHO started pressuring countries like Indonesia that were widely using hydroxychloroquine to ban it;[261] and some countries—including France, Italy, and Belgium—decided to stop using it for COVID-19.[262]

The problem, however, is that the study was based on false data from a company named Surgisphere, whose founder and CEO Sapan Desai was a co-author on the published paper.[263] The data were so obviously flawed that journalists and outside researchers began raising concerns within days of the paper's publication.[264] Even the Lancet's editor in chief, Dr. Richard Horton, admitted that the paper was a "fabrication," "a monumental fraud,"[265] and "a shocking example of research misconduct in the middle of a global health emergency."[266] Approximately two weeks after its publication, the paper was retracted.[267] An article published in *The Guardian* declared that "[g]iven the seriousness of the topic and the consequences of the paper, this [was] one of the most consequential retractions in modern history."[268] Despite calls to "publish full explanations

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259 *Id.* at 1.

260 James Heathers, *The Lancet has made one of the biggest retractions in modern history. How could this happen?*, The Guardian (Jun. 5, 2020), *available at* https://www.theguardian.com/commentisfree/2020/jun/05/lancet-had-to-do-one-of-the-biggest-retractions-in-modern-history-how-could-this-happen (last visited Oct. 14, 2021).

261 Kate Lamb & Tom Allard, *Indonesia, major advocate of hydroxychloroquine, told by WHO to stop using it*, Reuters (May 26, 2020), *available at* https://www.reuters.com/article/us-health-coronavirus-indonesia-chloroqu/exclusive-indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it-idUSKBN23227L (last visited Oct. 14, 2021).

262 *France, Italy, Belgium act to stop use of hydroxychloroquine for COVID-19 on safety fears*, Reuters (May 27, 2020), *available at* https://www.reuters.com/article/health-coronavirus-hydroxychloroquine-fr/update-1-france-italy-belgium-act-to-stop-use-of-hydroxychloroquine-for-covid-19-on-safety-fears-idUKL1N2D911J (last visited Oct. 14, 2021).

263 Boseley & Davey, *supra*.

264 Davey, *supra*.

265 Rabin, *supra*.

266 Boseley & Davey, *supra*.

267 *Id.*

268 Heathers, *supra*.

of what happened," the Lancet has "declined to provide details regarding the retracted stud[y]."[269]

Further reducing the cardiac concerns is important information on the FDA's own website. The FDA "cautions against use of hydroxychloroquine . . . for COVID-19 *outside of the hospital setting* or a clinical trial due to risk of heart rhythm problems."[270] But the agency's referenced support for this cautionary statement concerning *nonhospitalized patients* is its "review of safety issues with the use of hydroxychloroquine . . . to treat *hospitalized patients* with COVID-19."[271] It is questionable, however, to theorize about risks to nonhospitalized patients with mild COVID-19 based on data about heart issues in hospitalized patients with severe COVID-19 because, as explained above, cardiac complications often accompany the late stages of COVID-19. The FDA's concerns thus derive from a context—using hydroxychloroquine to treat hospitalized patients—that we are not addressing in this opinion.

It is important to note that although the medical literature tends to confirm that hydroxychloroquine is a safe medication when used in appropriate doses, any concerns about heart issues, even if resting on limited evidence, are serious. Prevailing principles of informed consent likely require physicians who present patients with the option of using hydroxychloroquine for early treatment of COVID-19 to inform them about the cardiac concerns that the FDA has identified. Also, for patients who have underlying cardiac issues, physicians should carefully consider whether hydroxychloroquine is the right choice for them. Finally, physicians should pay attention to which drugs they combine with hydroxychloroquine and evaluate the potential cardiac risks of those combinations. Failure to take such precautions could result in disciplinary action.

iii. U.S. Public Health Agencies on Hydroxychloroquine

The public health agencies in the United States have addressed the topic of hydroxychloroquine and COVID-19. The NIH "recommends against" its use "for the treatment of COVID-19 in hospitalized patients . . . and in nonhospitalized patients."[272] To justify its position against hydroxychloroquine for nonhospitalized patients, the NIH relied heavily on a RCT conducted by Mitja.[273] While that study did not show great advantages in the hydroxychloroquine group, that group did have, as the NIH's own

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269 Rabin, *supra*.

270 U.S. Food and Drug Administration, FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or (last visited Oct. 14, 2021) (emphasis added).

271 *Id.* (emphasis added).

272 NIH, COVID-19 and Hydroxychloroquine, *supra*.

273 *Id.*

website reports, a slight reduction in the risk of hospitalization (7.1% risk in the control arm versus 5.9% risk in the treatment arm) and in the time to resolution of symptoms (12 days in the control arm versus 10 days in the treatment arm).[274] As for serious adverse events, more (12) were reported in the control group than the hydroxychloroquine group (8), and the researchers determined that the serious adverse events in the hydroxychloroquine group were not related to the drug.[275] Thus, this study, particularly when considered in light of the large-scale observational studies discussed above, appears to be an insufficient basis to definitively recommend against using hydroxychloroquine as an early COVID-19 treatment.

The FDA, for its part, has questioned not only hydroxychloroquine's safety, as we discussed above, but also its efficacy. The agency's position grew out of its approval and subsequent disapproval of an Emergency Use Authorization (EUA) involving hydroxychloroquine. That EUA was issued on March 28, 2020, and it authorized licensed healthcare providers to use hydroxychloroquine donated to the Strategic National Stockpile to treat patients hospitalized with COVID-19.[276] Though this EUA was necessary to authorize the use of a specific source of hydroxychloroquine for a specific purpose, it was not required to allow healthcare providers to prescribe hydroxychloroquine off-label for COVID-19. That option was already available, as our prior discussion of off-label use makes clear. When the FDA revoked the EUA a few months later, on June 15, 2020, that is when it stated its current position on hydroxychloroquine and COVID-19.[277]

In that revocation, the FDA said that it no longer "believe[s] that oral formulations of [hydroxychloroquine] . . . may be effective in treating COVID-19" or that "that the known and potential benefits of these products outweigh their known and potential risks."[278]

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274 National Institutes of Health, Table 2b. Chloroquine or Hydroxychloroquine and/or Azithromycin: Selected Clinical Data, https://www.covid19treatmentguidelines.nih.gov/tables/table-2b/ (last visited Oct. 14, 2021) (discussing Oriol Mitjà, *Hydroxychloroquine for Early Treatment of Adults With Mild Coronavirus Disease 2019: A Randomized, Controlled Trial*, Clinical Infectious Diseases (2020), *available at* https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1009/5872589 (last visited Oct. 14, 2021)).

275 *Id.* (discussing Mitjà, *supra*).

276 Letter from Denise M. Hinton, Chief Scientist, U.S. Food and Drug Administration, to Dr. Rick Bright, Director of Biomedical Advanced Research and Development Authority (BARDA), Office of Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS) (Mar. 28, 2020), *available at* https://www.fda.gov/media/136534/download (last visited Oct. 14, 2021).

277 Letter from Denise M. Hinton, Chief Scientist, U.S. Food and Drug Administration, to Gary L. Disbrow, Deputy Assistant Secretary, Director of Medical Countermeasure Programs, Biomedical Advanced Research and Development Authority (BARDA), Office of Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS) (Jun. 15, 2020), *available at* https://www.fda.gov/media/138945/download (last visited Oct. 14, 2021).

278 *Id.* at 2.

Because both the EUA and its revocation deal only with hydroxychloroquine's use in hospitalized patients, they do not address the treatment topic that we are considering in this opinion—hydroxychloroquine's use as an early COVID-19 treatment.

The FDA's EUA revocation included four justifications, none of which establishes—let alone by clear and convincing evidence—that hydroxychloroquine is ineffective as an early treatment of COVID-19. First, the FDA said that the "suggested dosing regimens . . . are unlikely to produce an antiviral effect" because they will not create sufficient "drug concentration" in the body.[279] But as the FDA's revocation itself acknowledged, hydroxychloroquine's "immunomodulatory effects," as opposed to its antiviral effects, are not "predicated on achieving [certain hydroxychloroquine] concentration[]" levels.[280] Moreover, the FDA based its views on the assumption that "free drug concentration in the plasma" are "likely to be equal to free extracellular tissue concentration."[281] But other researchers' simulations showed that hydroxychloroquine's "concentration in lung tissue was much higher than in plasma,"[282] leading them to conclude that moderate doses are "recommended to treat SARS-CoV-2 infection."[283] Thus, the FDA's pessimism about hydroxychloroquine's potential antiviral capacity is open to reasonable debate in the scientific community.

Second, the FDA wrote that "[e]arlier reports of decreased viral shedding" with hydroxychloroquine "treatment have not been consistently replicated."[284] Notice that the FDA did not say that the studies have *disproven* a reduction in viral shedding; rather, the agency recognized that the evidence was still evolving and that some studies did in fact observe a positive "impact on viral shedding."[285] This criticism, on its face, is thus insufficient to dismiss hydroxychloroquine's use as an early COVID-19 intervention. Additionally, doubts about hydroxychloroquine's effect on viral shedding question only one of the drug's many possible mechanisms of action against COVID-19. More salient

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279 U.S. Food and Drug Administration, Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate, at 1, 4, *available at* https://www.fda.gov/media/138945/download (last visited Oct. 14, 2021) (hereinafter, "FDA EUA Revocation Memo").

280 *Id.* at 4.

281 *Id.*

282 Xueting Yao et al., *In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)*, Clinical Infectious Diseases, at 13 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7108130/pdf/ciaa237.pdf (last visited Oct. 14, 2021).

283 *Id.* at 2.

284 FDA EUA Revocation Memo, *supra*, at 1.

285 *Id.* at 6.

information is whether the drug is actually decreasing hospitalization and mortality rates when used as an outpatient treatment. As we discussed above, many large observational studies strongly suggest that hydroxychloroquine does in fact keep people diagnosed with COVID-19 out of the hospital and alive. That evidence is far more relevant of the drug's potential efficacy as an early COVID-19 treatment than debates about viral shedding.

Third, the FDA found it compelling that "NIH guidelines now recommend against" using hydroxychloroquine "outside of a clinical trial."[286] But as previously explained, the NIH's recommendation concerning COVID-19 outpatients does not rest on undisputed support. Thus, the NIH's guidelines should not be considered a basis upon which to ban healthcare providers from using hydroxychloroquine for COVID-19.

Fourth, the FDA stressed that "[r]ecent data from a large randomized controlled trial"—the RECOVERY trial mentioned above—"showed no evidence of benefit . . . of [hydroxychloroquine] treatment in hospitalized patients with COVID-19."[287] Yet as we have already discussed, a study about hospitalized patients does not address hydroxychloroquine's efficacy as an outpatient COVID-19 treatment. Indeed, the RECOVERY team itself reported that while its "findings indicate that hydroxychloroquine is not an effective treatment for hospitalized patients with Covid-19," it does "not address [the drug's] use as prophylaxis or in patients with less severe SARS-CoV-2 infection managed in the community."[288] In sum, none of the FDA's four reasons, in isolation or taken together, clearly establish that hydroxychloroquine is ineffective as an early treatment against COVID-19.

Despite raising doubts about hydroxychloroquine's use against COVID-19, the FDA has consistently affirmed that healthcare providers retain the right to use hydroxychloroquine as a part of early COVID-19 treatment. At least four statements demonstrate this.

First, the FDA's current website says (and has said since July 2020) that "[i]f a healthcare professional is considering use of hydroxychloroquine or chloroquine to treat or prevent COVID-19, FDA recommends checking www.clinicaltrials.gov for a suitable clinical trial and consider enrolling the patient." This plainly assumes that healthcare providers have the right to use hydroxychloroquine to treat COVID-19.

Second, on May 29, 2020, then-FDA Commissioner Stephen Hahn acknowledged that "[m]any physicians have . . . prescribed [hydroxychloroquine] for patients with COVID-19 based on an individual assessment of the potential benefits versus the risks

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286 *Id.* at 1.

287 *Id.*

288 RECOVERY Collaborative Group, *Effect of Hydroxychloroquine in Hospitalized Patients with Covid-19*, 383 The New England Journal of Medicine 2030, 2038 (Nov. 2020), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022926?articleTools=true (last visited Oct. 14, 2021).

for an individual patient."[289] He added that "[p]rescribing a product for uses not specifically included in the official labeling is common in the practice of medicine" and that the FDA does not "prohibit[] physicians from prescribing medications" because the agency does "not regulate the practice of medicine."[290] These statements are still posted on the FDA's website, and we are not aware of any subsequent FDA statements revoking them.

Third, in June 2020, after the FDA revoked the hydroxychloroquine EUA, Health and Human Services Secretary Alex Azar said: "At this point, hydroxychloroquine and chloroquine are just like any other approved drug in the United States. They may be used in hospital, they may be used in out-patient, they may be used at home—all subject to a doctor's prescription."[291] Leaving no doubt about this point, Secretary Azar added that "[i]f a doctor wishes to prescribe [hydroxychloroquine], working with a patient, they may prescribe it for any purpose that they wish."[292] We are not aware of any subsequent statement revoking this guidance.

Fourth, in late July 2020, then-FDA Commissioner Hahn reiterated that "whether people should take hydroxychloroquine as a treatment" for COVID-19 is a decision that "should be made between a doctor and a patient."[293] He specifically stated: "A doctor and a patient need to assess the data that's out there, FDA does not regulate the practice of medicine, and that in the privacy of the doctor-patient relationship is where that decision should be made."[294]

iv. Foreign Public Health Agencies, Professional Associations, and Physicians on Hydroxychloroquine

The WHO "recommend[s] against administering hydroxychloroquine . . . for treatment of COVID-19" for "patients with any disease severity and any duration of symptoms."[295] It reached this recommendation after concluding that hydroxychloroquine

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289 FDA, Bringing Perspective, *supra*.

290 *Id.*

291 Trump White House Archives, Remarks by President Trump in Roundtable Discussion on Fighting for America's Seniors (Jun. 15, 2020), *available at* https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-roundtable-discussion-fighting-americas-seniors/ (last visited Oct. 14, 2021).

292 *Id.*

293 Tal Axelrod, *FDA chief: Hydroxychloroquine use a decision between doctor and patient*, The Hill (Jul. 30, 2020), https://thehill.com/policy/healthcare/509733-fda-chief-hydroxychloroquine-use-a-decision-between-doctor-and-patient?rl=1 (last visited Oct. 14, 2021).

294 *Id.*

295 WHO COVID-19 Guidelines, *supra*, at 26.

"probably do[es] not reduce mortality" and that its "effect on . . . admission to hospital . . . remains uncertain."[296] To the extent that this recommendation purports to address hydroxychloroquine's effectiveness as an early treatment for COVID-19, it arguably rests on weak evidence. Although it is difficult to determine how many of the studied individuals were outpatients, it appears that most were hospitalized. For instance, the WHO says that it consulted 29 studies in concluding that "[h]ydroxychloroquine probably does not reduce mortality," but the only study specifically cited is the RECOVERY trial,[297] which, as we already indicated, included only patients hospitalized with COVID-19.[298] In addition, the WHO's statistics on hospitalization rates, which consisted of one RCT that included 465 outpatients, suggests hydroxychloroquine's efficacy.[299] That trial revealed a hospitalization rate of 47 per 1,000 people in the control group but only 19 of 1,000 people in the hydroxychloroquine arm.[300] It thus seems as if the WHO may have overreached in definitively declaring that hydroxychloroquine holds no promise as an early COVID-19 treatment.

The WHO also "recommend[s] against administering hydroxychloroquine prophylaxis to individuals who do not have COVID-19" because it believes that prophylaxis "hydroxychloroquine has a small or no effect on death and hospital admission" and that it "probably has a small or no effect on laboratory-confirmed COVID-19."[301] Disagreeing with this, the team of researchers conducting the COPCOV trial on prophylaxis hydroxychloroquine has announced that the WHO's conclusions are "scientifically unsound."[302] In their statement on this topic, the COPCOV team explained that the available RCTs "suggest substantial uncertainty as to the benefit of hydroxychloroquine in preventing COVID-19," but the "overall trend [is] towards benefit."[303]

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296 *Id.* at 27.

297 *Id.* at 28.

298 RECOVERY Collaborative Group, *supra*, at 2030.

299 WHO COVID-19 Guidelines, *supra*, at 29.

300 *Id.*

301 World Health Organization, WHO Living guideline: Drugs to prevent COVID-19, at 12 (Mar. 2, 2021), *available at* https://apps.who.int/iris/bitstream/handle/10665/339877/WHO-2019-nCoV-prophylaxes-2021.1-eng.pdf?sequence=13&isAllowed=y (last visited Oct. 14, 2021).

302 The COPCOV Trial's position statement on "A living WHO guideline on drugs to prevent COVID-19," MORU Tropical Health Network (Mar. 5, 2021), https://www.tropmedres.ac/news/copcov-response-to-latest-who-guidelines-on-hydroxychloroquine-for-covid-19-trials-1 (last visited Oct. 14, 2021).

303 *Id.*

As for the professional associations' and physician groups' views on hydroxychloroquine, it appears that they generally adopt the same position they took on ivermectin. Those like the AAPS that support ivermectin as an option for early COVID-19 treatment generally support hydroxychloroquine too, while those like the AMA, APhA, and ASHP that oppose one typically resist the other. Additionally, many physician groups use early COVID-19 treatment protocols that include hydroxychloroquine. For example, an article co-authored by over 50 doctors in Reviews in Cardiovascular Medicine outlines an early treatment protocol that includes hydroxychloroquine as a key component.[304]

Considering the evidence discussed above, we do not find that clear and convincing evidence would warrant disciplining physicians who prescribe hydroxychloroquine for the prevention or early treatment of COVID-19 after first obtaining informed patient consent.

CONCLUSION

Based on the available data, we do not find clear and convincing evidence that a physician who first obtains informed consent and then utilizes ivermectin or hydroxychloroquine for COVID-19 violates the UCA. This conclusion is subject to the limits noted throughout this opinion. Foremost among them are that if physicians who prescribe ivermectin or hydroxychloroquine neglect to obtain informed consent, deceive their patients, prescribe excessively high doses, fail to check for contraindications, or engage in other misconduct, they might be subject to discipline, no less than they would be in any other context.

As we have stressed throughout, this opinion is based only on the data and information available at this time. If the relevant medical evidence materially changes, that could impact our conclusions. Also, though an opinion from our office about possible UCA violations would ordinarily focus on healthcare practices within Nebraska, the context of a global pandemic necessitates looking for evidence far beyond our State's borders, as we have done here. Thus, the analytical roadmap in this opinion likely has limited application outside the circumstance of a global pandemic.

We emphasize in closing that our office is not recommending any specific treatments for COVID-19. That is not our role. There are multiple treatment options outside the scope of this opinion—including treatments that have been officially approved by the FDA—that physicians and their patients should carefully consider. This opinion takes no position on them. Rather, we address only the off-label early treatment options discussed in this opinion and conclude that the available evidence suggests that they might work for some people. Allowing physicians to consider these early treatments will free them to evaluate additional tools that could save lives, keep patients out of the hospital, and provide relief for our already strained healthcare system.

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304 McCullough, *Multifaceted*, *supra*, at 522-23.

Very truly yours,

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